NIOSH/NPPTL Total Inward Leakage Public Meeting

June 26, 2007

The Embassy Suites Pittsburgh International Airport Hotel

Coraopolis, Pennsylvania

NIOSH/NPPTL Total Inward Leakage Public Meeting

- *Disclaimer: The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.*

NIOSH/NPPTL Total Inward Leakage Public Meeting

Meeting Purpose

– Discussion of Respirator Fit Test Panel

– Discussion of Half Mask Testing & Analysis

– Proposed Criteria for Total Inward Leakage Performance Requirement

Meeting Agenda

- **Welcome/Opening Remarks – Les Boord/Jon Szalajda**
- **Program Concept – Bill Newcomb**
- **Anthropometrics Research to Develop Fit Test Panels - Ziqing Zhuang**
- **IOM Report – Les Boord/ Andy Pope/Ron Shaffer**
- **Half-Mask Testing Results – Bill Newcomb**
- **Proposed Criteria and Implementation Plan – Bill Newcomb**
- **Statistical Explanations – Doug Landsittel**
- **NPPTL TIL Testing Capabilities – Jon Szalajda**
- **Questions and Answers / Comment Period**

Docket Information

- **Mail:**
  - **NIOSH Docket Office**
  - **Robert A. Taft Laboratories, M/S C 34**
    - **TIL - NIOSH 036**
  - **4676 Columbia Parkway**
  - **Cincinnati, OH 45226**
- **Email: niocindocket@cdc.gov**
- **Fax: (513) 533-8285**
- **Phone: (513) 533-8303**
- **NPPTL Web Site: http://www.cdc.gov/niosh/npptl**

NIOSH/NORA Research Program Portfolio

Industry Sectors	Cross Sector Programs	Emphasis Areas
•Agriculture, forestry, and fishing •Construction •Healthcare and social assistance •Mining •Manufacturing •Services •Transportation, warehousing, and utilities •Wholesale and retail trade	▪Authoritative Recommendations Development ▪Cancer, reproductive, cardiovascular, neurologic & renal diseases • Communications and information dissemination • Emergency preparedness/response • Global collaborations • Health hazard evaluation (HHE) • Hearing loss prevention • Immune, dermal and infectious diseases • Musculoskeletal disorders • Personal protective technology • Radiation dose reconstruction • Respiratory diseases • Training grants • Traumatic injury • Work organization and stress-related disorders	• Economics • Exposure assessment • Engineering controls • Work life initiative • Occupational health disparities • Small business assistance and outreach • Surveillance

NIOSH PPT / NPPTL
Vision & Mission

The **VISION** is to be the leading provider of quality, relevant, and timely PPT research, training, and evaluation.

The **MISSION** of the PPT cross sector program within NIOSH is to prevent work-related injury and illness by advancing the state of knowledge and application of personal protective technologies (PPT).

PPT in this context is defined as the technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment worn by individuals to reduce the effects of their exposure to a hazard.

FY 2008 Project Planning Guide

PPT Cross Sector Goals

- **Strategic Goal 1: Reduction of Inhalation Hazards**

- **Strategic Goal 2: Reduction of Dermal Hazards**

- **Strategic Goal 3: Reduction of Injury Hazards**

- **Intermediate goals for each strategic goal:**

  – Comprehensive research

  – Harmonized PPT standards development

  – Evaluation activities

  – r2p → communications & outreach

William Newcomb
Physical Scientist

June 26, 2007

NIOSH

- **30 CFR 11**
  - 1972
  - Schedule 21C
  - Coal dust test abolished
  - Isoamyl acetate test
    - Configuration issues
- **42 CFR Part 84**
  - 1995
  - Isoamyl acetate test eliminated
  - Undefined NIOSH effectiveness studies for isoamyl acetate or ANSI/OSHA accepted fit testing
  - OSHA individual fit testing
  - Best practices used in a quality respirator program

Lack of Fit Testing

- *Respirator Usage in Private Sector Firms, 2001*
    - Only 53% of respondents conduct fit tests
- **OSHA public hearing on the proposed revision to 29 CFR Part 134**
    - Table for assigned protection factors
    - Maximum use concentrations
- **During the hearings, NIOSH committed to add a quantifying fit method to respirator certification requirements**

Respirator Usage in Private Sector Firms, 2001

Total Inward Leakage Program

- **As a continuation of NIOSH's unique modular approach to Standards Development, a program was established to TIL requirements for:**

  1. Half-mask particulate respirators

  2. PAPR and supplied-air respirators

  3. All other respirators

  4. Other PPE, e.g., encapsulating suits

Total Inward Leakage Program

- **Phase 1: Investigative/concept draft**

  – Gather and review existing TIL respirator information

  – Review existing TIL test equipment capabilities and technical specifications

  – Identify a peer review team composed of manufacturers, users, academia and government

  – Develop initial TIL concept addressing performance requirements and test protocol

  – Conduct peer review and a public meeting

  – Establish technical specification for TIL test facility

Total Inward Leakage Program

- **Phase 2: Test facility/benchmark testing**

  - Establish NPPTL TIL test facility

  - Perform benchmark testing to establish state of the art respirator performance

  - Continue development of TIL concept requirements and protocols

  - Identify draft implementation plan

Total Inward Leakage Program

- **Phase 3: Consistency testing and implementation plan**

    – Conduct validation testing for TIL facility

    – Finalize implementation plan

    – Finalize TIL concept requirements and protocols

TIL Certification Performance Criteria

- **Not a substitute for OSHA mandated individual fit-testing**
    - Only method of accessing individual fit is a fit test
    - No respirator can be certified to fit

TIL Certification Performance Criteria

- **Establish certification performance criteria**

  - Based on actual fit factor results, not based on APF
  - Inappropriate to use previously obtained fit-test data
  - Conduct benchmark testing on state-of-the-art respirators within class
  - Rely on the manufacturer's User Instructions
  - Use entire panel for TIL evaluation

Total Inward Leakage Program

- **For the half-mask project the following test method characteristics were compared:**

    - Ability to be used to measure TIL on all styles of halfmasks, quartermasks and filtering facepieces regardless of air purifying element

    - Required sensitivity for the desired results

    - Ability to give accurate, repeatable results

    - Ability to do required test exercises without disturbing the fit due to test equipment, probes, etc

    - Ease of duplication (i.e., intra-lab reproducibility)

    - Cost of equipment

    - Need for a test chamber

    - Ease of preparation, use, clean up, etc

Total Inward Leakage Program

- **Best choice for measuring half-mask respirator TIL is PortaCount® Plus with N95-Companion™ in a direct reading mode**

- **Most reproducible exercise methods are thought to be those used in the OSHA fit test protocol**

  – A standard workplace with standardized movements does not exist

Total Inward Leakage Program

Face Width (mm)

Face Length (mm)
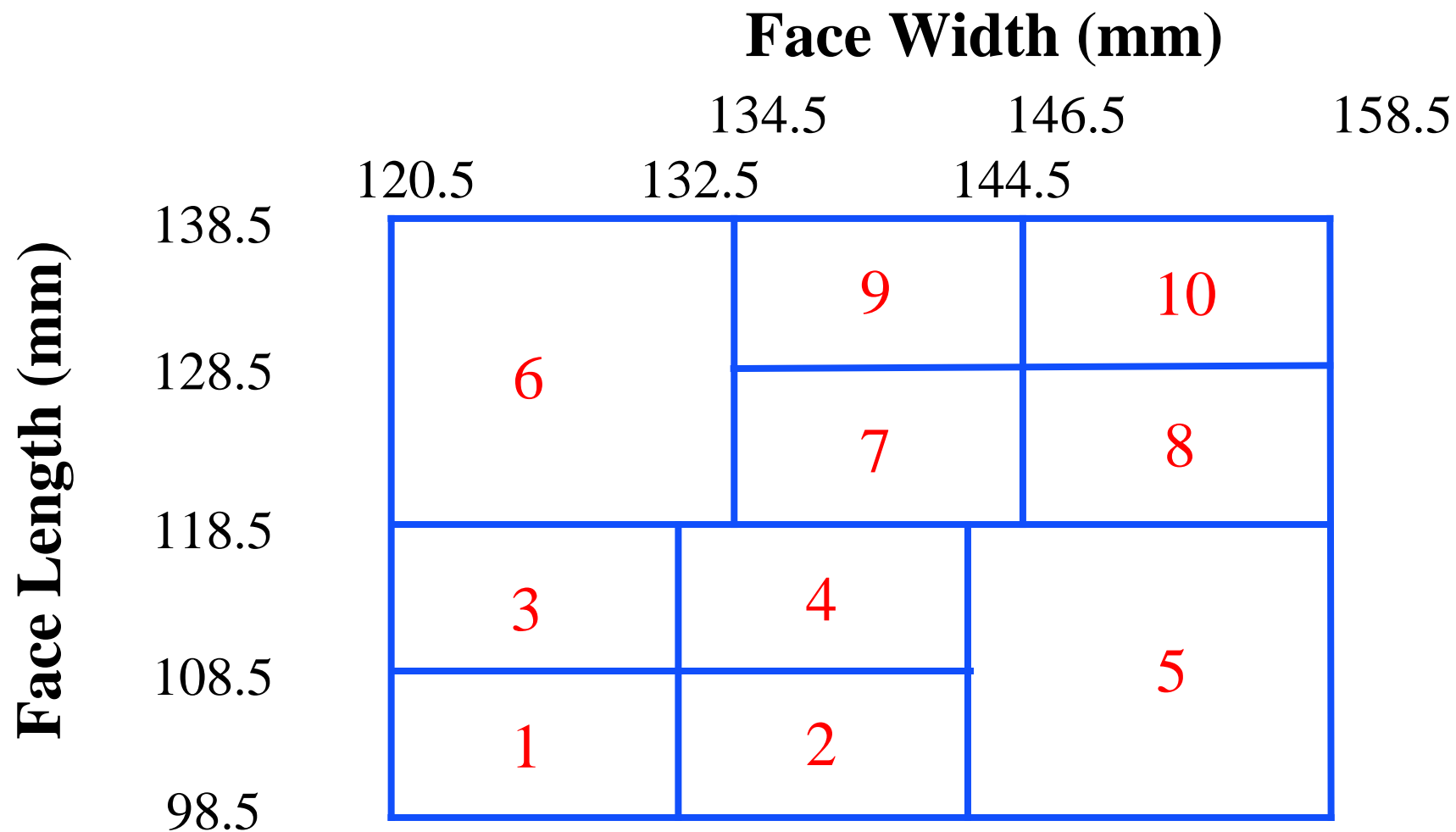
Total Inward Leakage Program

- **Summary**

  – Phase 2 is complete, in Phase 3

  – The study was designed to assess the overall capabilities of individual respirators

  – The Benchmark Data was derived by testing across the complete panel regardless of respirator size designation and therefore does not represent actual field use

  – The Data was analyzed in several different ways, and conclusions have been reached concerning proposed requirements for Certification
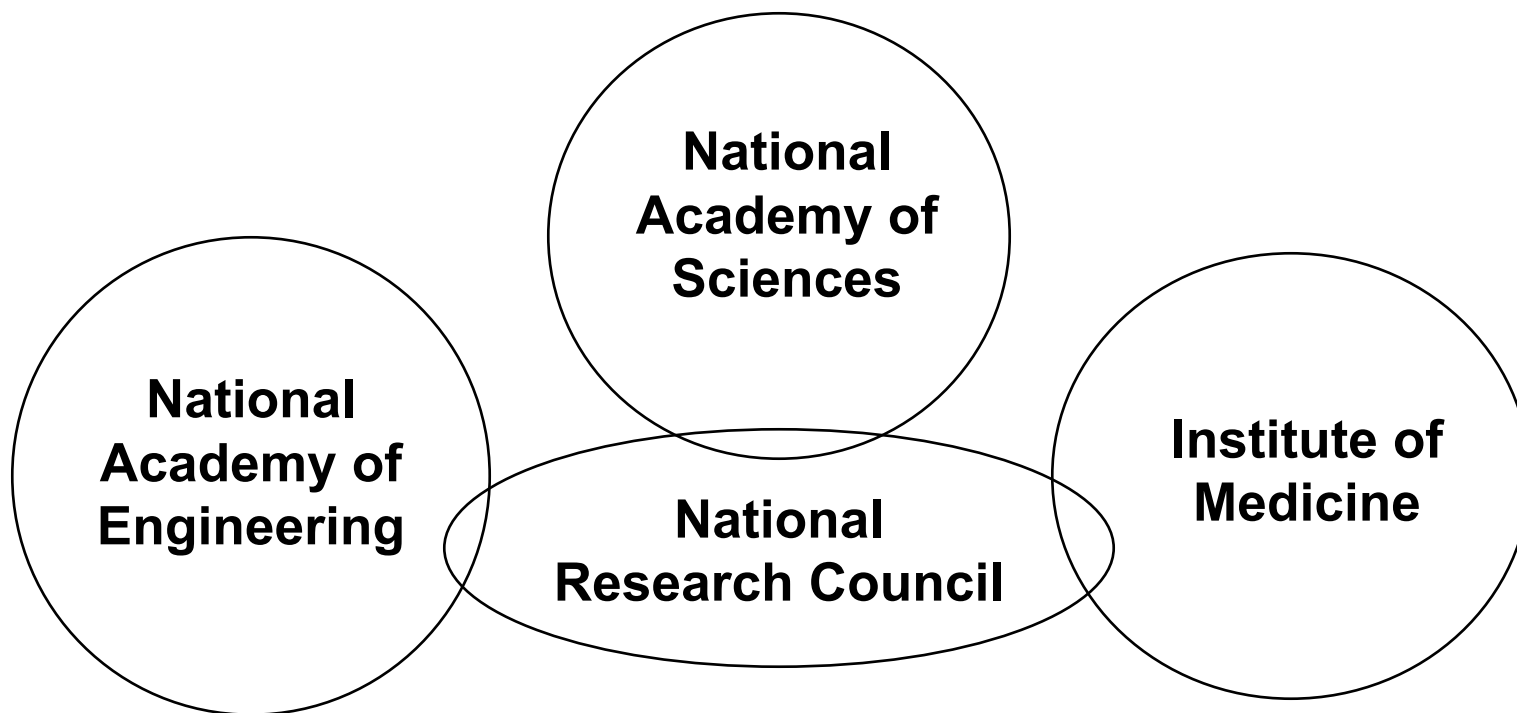
NIOSH Public Meeting: Total Inward Leakage

Andrew Pope, Ph.D.
Director
Board on Health Sciences Policy
Institute of Medicine

June 26, 2007

What I will cover today:

➢ **What is the IOM**

➢ **IOM Report: Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users**
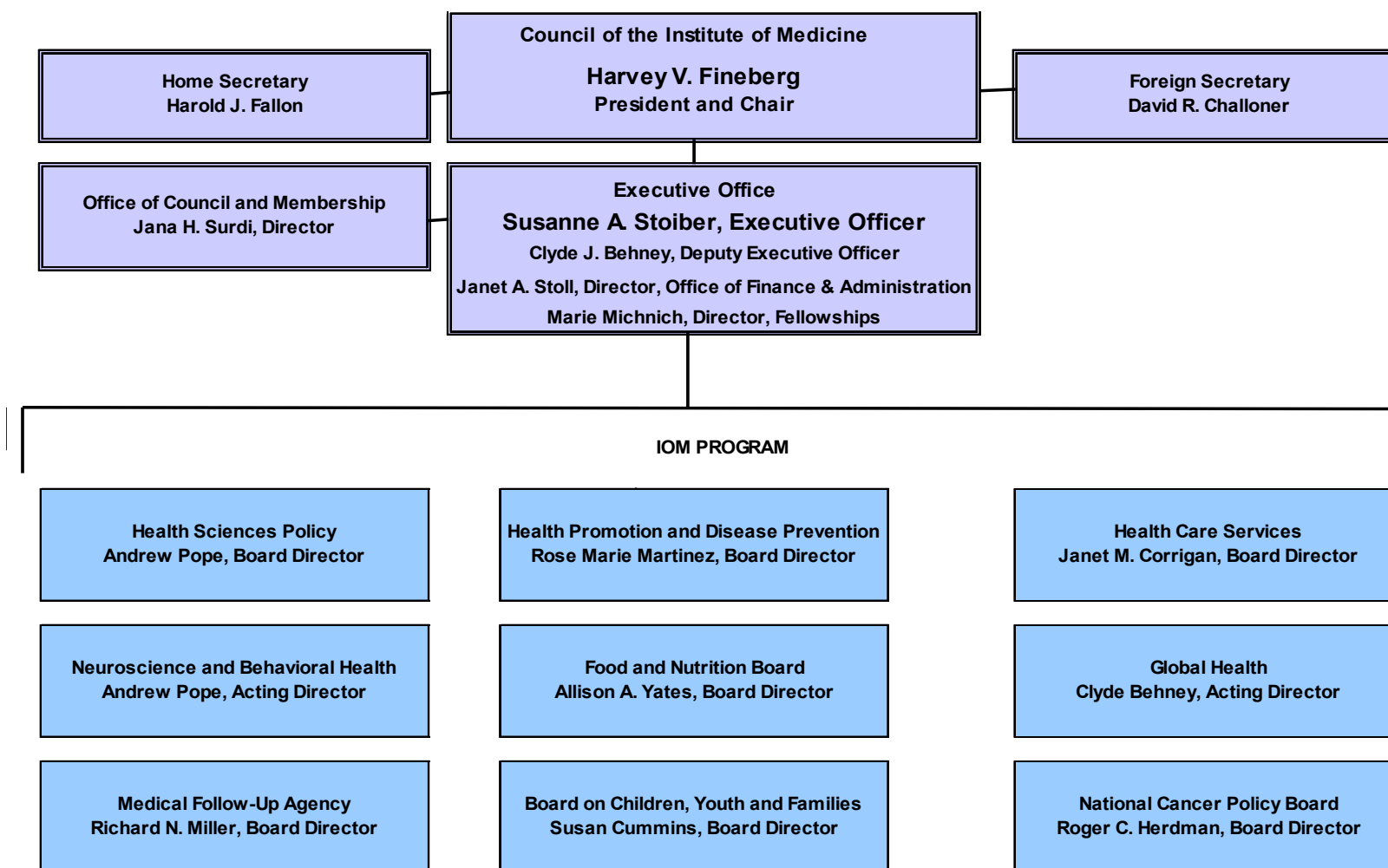
The National Academies

History of Origins

- ## 1863 – NAS Charter

- ## 1916 – NRC Established

- ## 1964 – NAE Established

- ## 1970 – IOM Established

CONGRESSIONAL CHARTER FOR THE NATIONAL ACADEMY OF SCIENCES

… the Academy shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art …

Approved, March 3, 1863.

ABRAHAM LINCOLN, President.

Council of the Institute of Medicine

Harvey V. Fineberg
President and Chair

Home Secretary
Harold J. Fallon

Foreign Secretary
David R. Challoner

Office of Council and Membership
Jana H. Surdi, Director

Executive Office
Susanne A. Stoiber, Executive Officer
Clyde J. Behney, Deputy Executive Officer
Janet A. Stoll, Director, Office of Finance & Administration
Marie Michnich, Director, Fellowships

IOM PROGRAM

Health Sciences Policy
Andrew Pope, Board Director

Health Promotion and Disease Prevention
Rose Marie Martinez, Board Director

Health Care Services
Janet M. Corrigan, Board Director

Neuroscience and Behavioral Health
Andrew Pope, Acting Director

Food and Nutrition Board
Allison A. Yates, Board Director

Global Health
Clyde Behney, Acting Director

Medical Follow-Up Agency
Richard N. Miller, Board Director

Board on Children, Youth and Families
Susan Cummins, Board Director

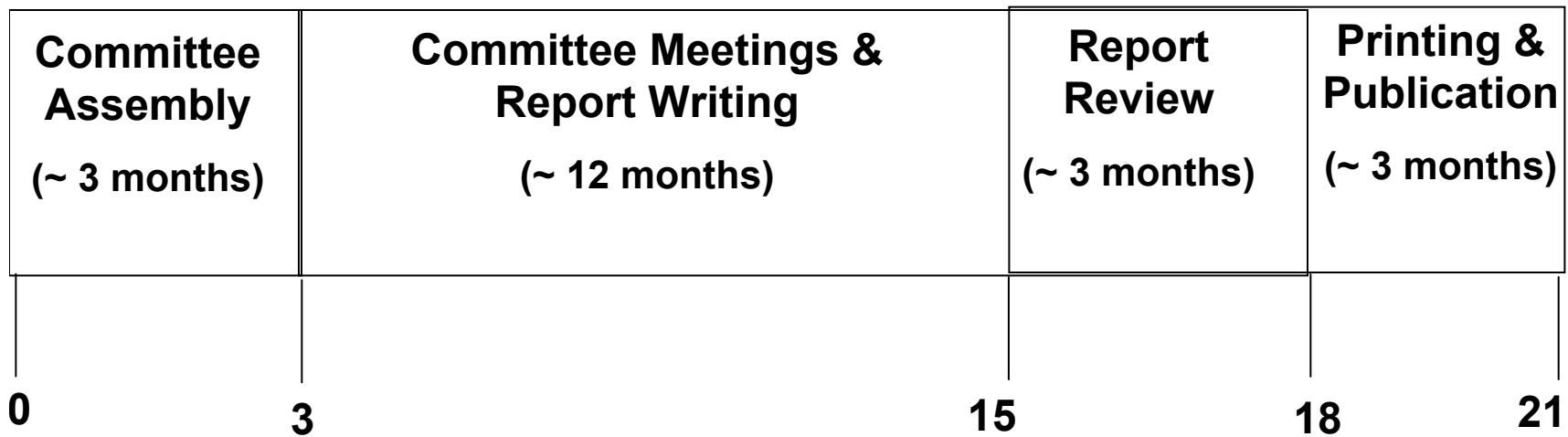**National Cancer Policy Board**
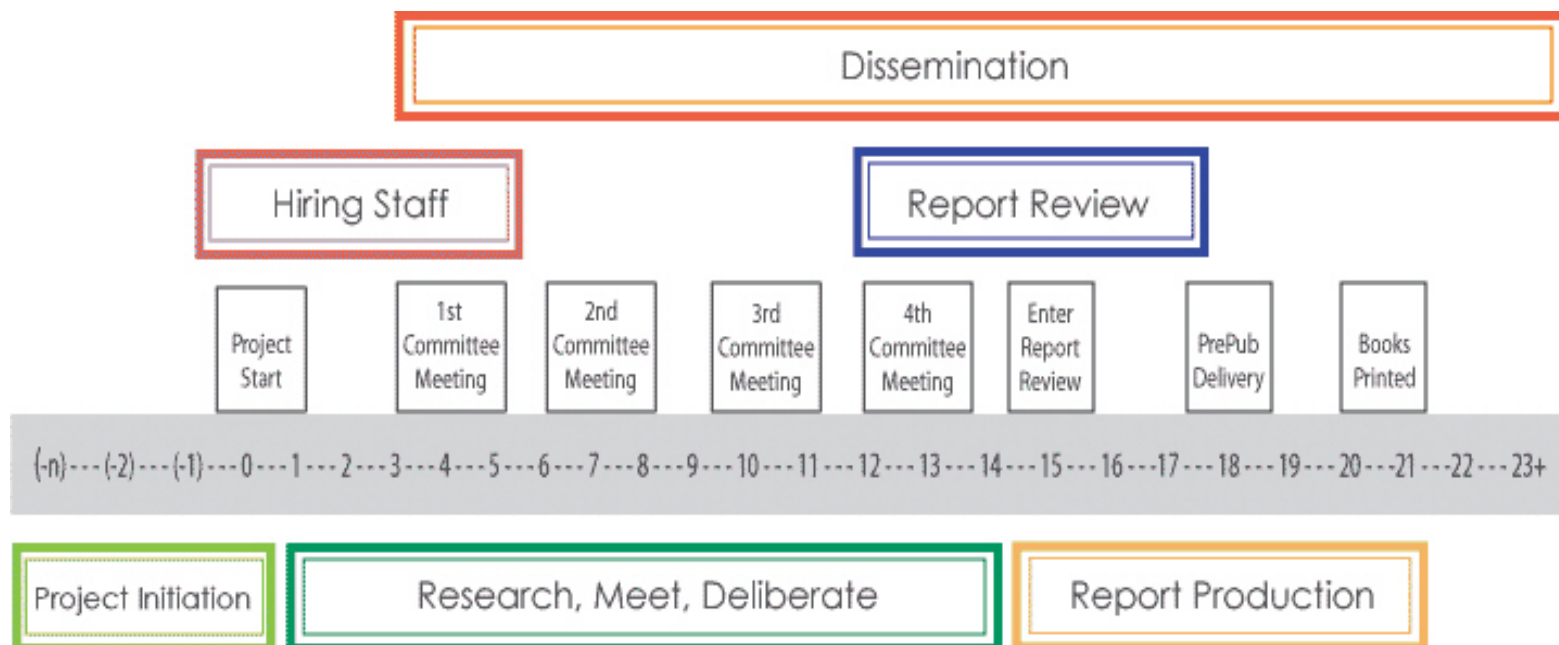Roger C. Herdman, Board Director

Study Initiation

- **Congressional Mandate**

- **Agency Request**
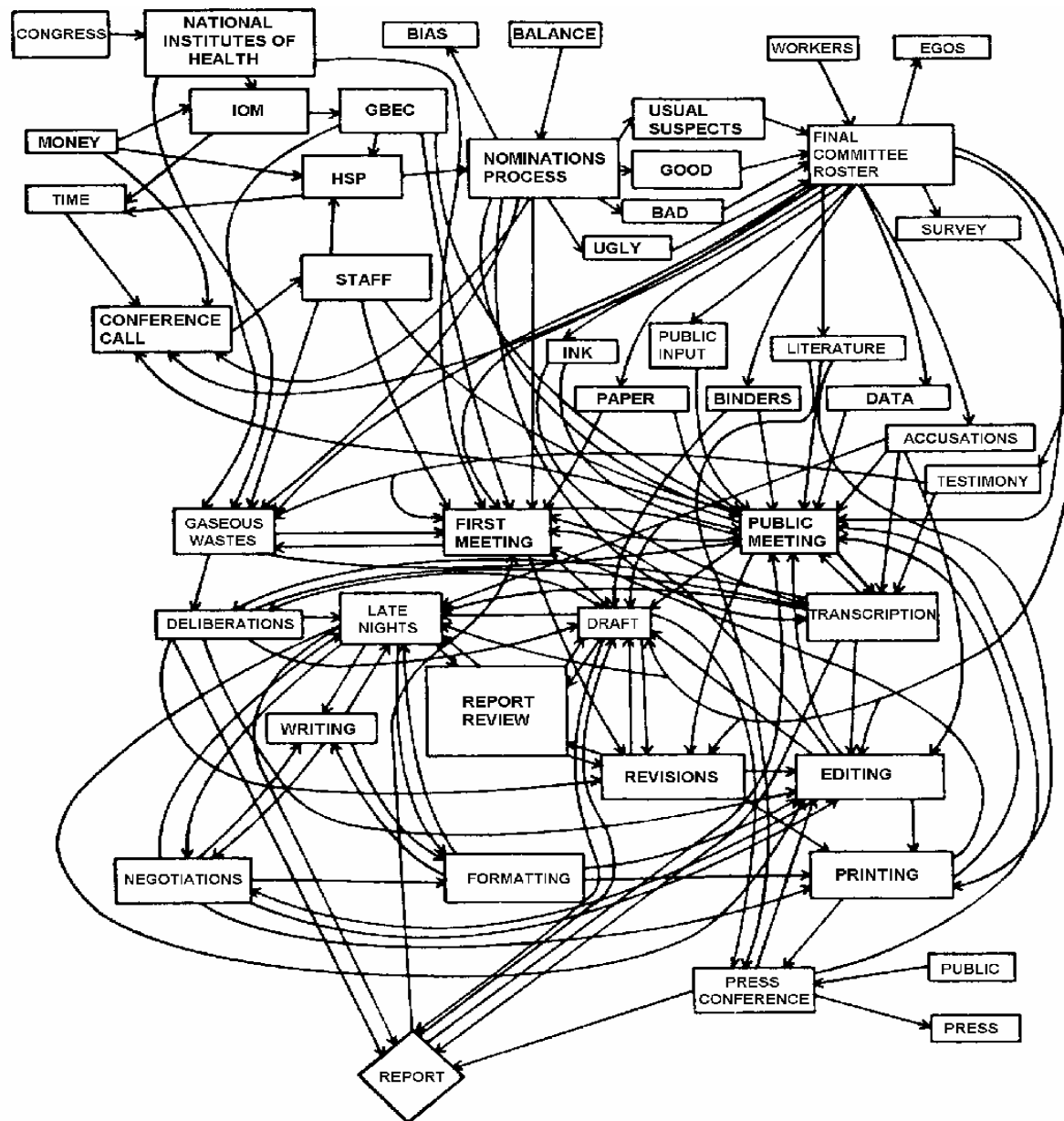
- **Self-Initiated**

Unique Strengths

- Reputation for independence and objectivity

- Stature of Academies' membership

- Ability to get the very best to serve

- *Pro bono* nature of committee service

- Special relationship to government

- Quality assurance and control procedures

Timeline of the Committee Process

Committee Assembly (~ 3 months)	Committee Meetings & Report Writing (~ 12 months)	Report Review (~ 3 months)	Printing & Publication (~ 3 months)

0   3   15   18   21

Dissemination

Hiring Staff

Report Review

| Project Start | 1st Committee Meeting | 2nd Committee Meeting | 3rd Committee Meeting | 4th Committee Meeting | Enter Report Review | PrePub Delivery | Books Printed |

(-n)---(-2)---(-1)---0---1---2---3---4---5---6---7---8---9---10---11---12---13---14---15---16---17---18---19---20---21---22---23+

Project Initiation

Research, Meet, Deliberate

Report Production

- *Committee on PPE for the Workforce (COPPE)*
  - Three open meetings in FY06
  - Meeting 1 FY07:   Oct 23-24, 2006
  - Workshop: Feb 22, 2007 – **PPE during an Influenza Pandemic: Research, Standards, Certification and Testing Directions**

- *Review of Anthropometrics Survey and Respirator Panel Modifications*
  - Three open meetings in FY06
  - Final report released Jan 2007

- *Review of BLS Survey of Respirator Use*
  - Three open meetings in FY06
  - Final report released Feb 2007

- *National Academies Evaluation of Personal Protective Technology (PPT) Cross Sector*
  - Evidence package to National Academies Aug 2007
  - National Academies evaluation Sept 2007
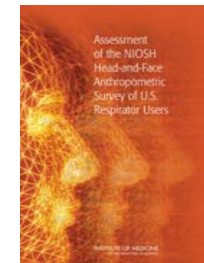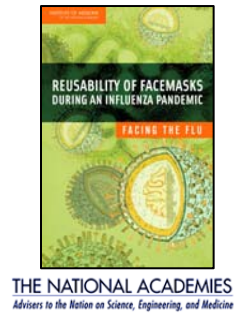
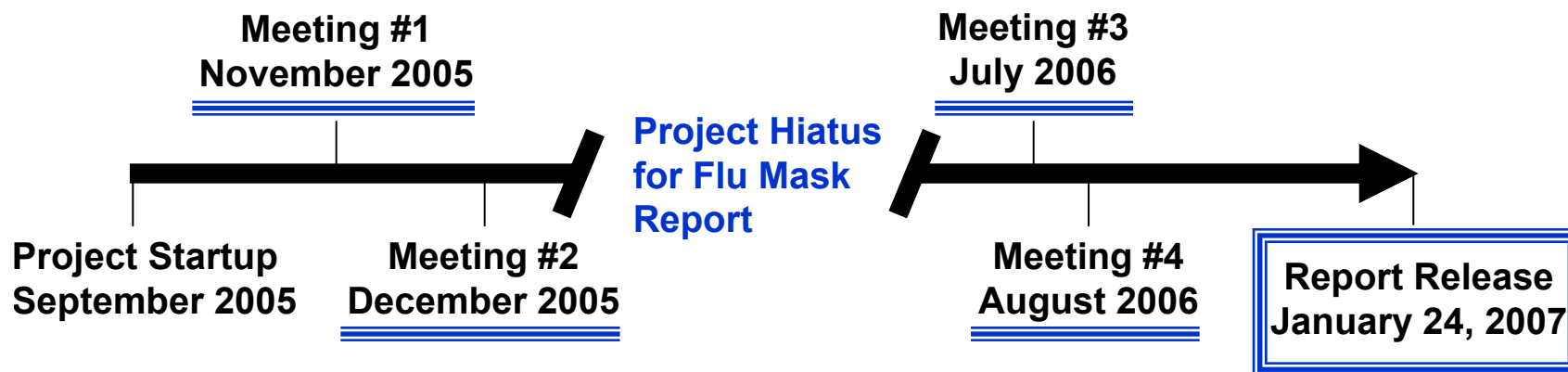# Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users
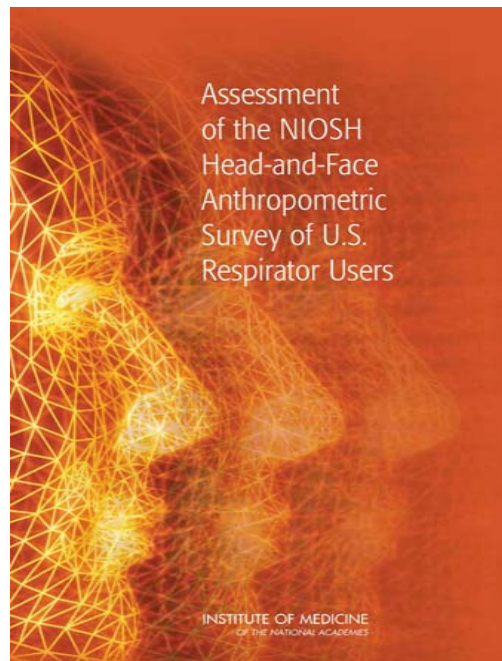
Abbreviated Statement of Task

- Examine the content and the form of the study, the sample and its sample methodology, and the adequacy of the resultant data.

- Determine if the revised panel is representative of the U.S. workforce and the adequacy of the anthropometric features and parameters considered in the revised panel.

- Identify additional analyses that NIOSH might undertake.

- Examine how the data obtained from the study was analyzed, conclusions reached from the data, and recommend additional information that NIOSH might derive from current and possible future efforts.

Committee Roster

JOHN C. BAILAR III, (*Chair*), **University of Chicago, Illinois**

LISA M. BROSSEAU, **University of Minnesota, Minneapolis**

HOWARD J. COHEN, **University of New Haven, West Haven, Connecticut**

ALAN L. HACK, **Los Alamos, New Mexico**

SUBHASH R. LELE, **University of Alberta, Edmonton, Canada**

YOUCHENG LIU, **Yale University School of Medicine, New Haven, Connecticut**

JOAN T. RICHTSMEIER, **Pennsylvania State University, University Park**

KNUT RINGEN, **Seattle, Washington**

JAVIER ROJO, **Rice University, Houston, Texas**

ALBERT A. SCIARRETTA, **CNS Technologies, Inc., Springfield, Virginia**

Project Timeline

Meeting #1
November 2005

Meeting #3
July 2006

Project Hiatus for Flu Mask Report

Project Startup September 2005

Meeting #2 December 2005

Meeting #4 August 2006

Report Release January 24, 2007

Major Findings: Overarching Themes

1. The results of the NIOSH-sponsored Anthrotech study represent a clear improvement over the anthropometric data and corresponding LANL fit-test face panels that have been used since the 1970s;

2. The NIOSH-sponsored Anthrotech study has a number of weaknesses that limit its effectiveness and reliability.

3. There are certain steps that should be taken to address the weaknesses, in order to move toward more effective testing and certification of respirators in the future.
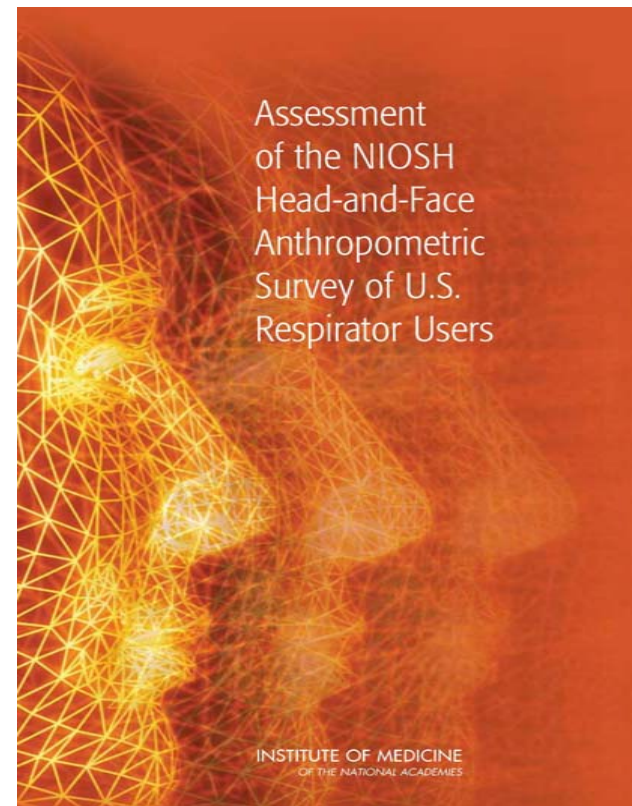
For More Information

Report Available at:

www.nap.edul

Andrew Pope:

apope@nas.edu

Assessment
of the NIOSH
Head-and-Face
Anthropometric
Survey of U.S.
Respirator Users

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Statistical Explanations for Development of the TIL Criteria

Doug Landsittel
Statistician/Senior Fellow

June 26, 2007

CDC Workplace Safety and Health

NIOSH

NPPTL *Research to Practice through Partnerships*

Outline

- **Overall statistical objectives**

  – NIOSH test panel

- **Statistical justification for an optimal criteria**

- **Example calculations and proposed criteria**

  – Interpret results

- **Summary and conclusions**

Overall Statistical Objectives

- **Initial considerations:**
  - Test a representative panel
  - Specify an acceptable TIL (≤ 5%)
- **TIL ≠ APF**
- **View TIL criteria as a statistical test**
  - Define concepts for an optimal test
  - Adequate number of subjects
  - Minimum % of subjects with acceptable TIL

NIOSH Test Panel

- **Eligibility screening**
  - Facial dimensions fit within the PCA Panel

- **Bivariate panel based on face width and length**
  - 35 total subjects from 10 different cells
  - Cell frequencies representative of U.S. workforce

- **Random selection of available subjects from within each cell of the panel**
  - Goal: avoid systematic error in subject selection
  - Other facial dimensions may be significant

Statistical Justification: Overall Concepts

- **<u>Assumption</u>: for a given model, an unknown % of subjects achieve acceptable fit**
  - Effectiveness of the model is judged by the % of subjects with acceptable fit across the population

- **<u>Overall Goal</u>: formulate a criteria with the following characteristics**
  - A highly effective model almost always passes
  - An ineffective model almost always fails

Statistical Justification: Overall Concepts

- **Follow-up questions:**

  - What defines an effective versus ineffective model?

  - How many subjects do we test?

  - What defines 'almost always'?

- **Answers to all 3 questions are inter-related**

- **Use standard statistical calculations to assess results under different assumptions**

  - Calculate probabilities using the binomial distribution

Statistical Justification: Initial Assumptions

- **Consider a model that is > 80% effective**

  – Should almost always pass the test

- **Consider a model that is < 60% effective**

  – Should almost always fail the test

- **Between 60% and 80% effective**

  – Expect variability in results

- **Sample size and defining 'almost always'**

  – Larger sample size will give more certainty

Statistical Justification:
Selected Results with 25 Subjects

- **Require 15/25 (60%) to achieve acceptable fit**
  - A model which is 85% effective will fail <0.1% of tests
  - A model which is 55% effective will fail 62% of tests
- **Require 19/25 (76%) to achieve acceptable fit**
  - A model which is 85% effective will fail 7% of tests
  - A model which is 55% effective will fail 97% of tests
- **19/25 provides a better criteria**
  - Models in the effective range fail more often
    - 90% effective will fail <1% of tests
  - Far more certainty in rejecting ineffective models

Statistical Justification: Selected Results with 35 Subjects

- **Require 21/35 (60%) to achieve acceptable fit**
  - A model which is 85% effective will fail <<0.1% of tests
  - A model which is 55% effective will fail 66% of tests
- **Require 26/35 (74%) to achieve acceptable fit**
  - A model which is 85% effective will fail 3% of tests
  - A model which is 55% effective will fail 98% of tests
- **26/35 provides a better criteria**
  - Models in the effective range fail more often, but still rare
    - 90% effective will fail <0.2% of tests
  - More certainty in rejecting ineffective models

Statistical Justification: Selected Results with 50 Subjects

- **Require 30/50 (60%) to achieve acceptable fit**
  - A model which is 85% effective will fail <<0.1% of tests
  - A model which is 55% effective will fail 71% of tests
- **Require 37/50 (74%) to achieve acceptable fit**
  - A model which is 85% effective will fail 1% of tests
  - A model which is 55% effective will fail >99% of tests
- **37/50 provides a better criteria**
  - Models in the effective range rarely fail
    - 90% effective will fail <0.1% of tests
  - More certainty in rejecting ineffective models

Summary of Results

- **Requiring about ¾ of subjects to achieve acceptable fit gives optimal results**

  - Lower criteria often pass ineffective models

  - Higher criteria often fail effective models

- **Larger sample sizes give more optimal results**

  - Increase from 25 to 35 gives a larger improvement

  - Need to balance practical and statistical issues

- **Proposed Criteria: 26/35 achieve a TIL ≤ 5%**

Reproducibility of a Single Test Result

- **26/35 represents a minimally passing result**
- **Designed to achieve optimal results**
  - Given an effective model → pass
  - Given an ineffective model → fail
  - Converse is not necessarily true
  - Either passing or failing may reflect a marginally effective model (say 70% effective)
- **Reproducibility requires a higher standard than 26/35 (76%)**

Summary and Conclusions

- **Select 35 subjects based on the NIOSH panels**
- **Specify ≤5% TIL as acceptable fit**
  - TIL ≠ APF
- **Specify 26/35 as the minimum fraction of subjects required to achieve acceptable fit**
- **Yields optimal statistical properties**
  - Models which provide acceptable fit for at least 80-85% of subjects will pass a high % of the tests
  - Models which provide acceptable fit for no more than 60% of subjects will fail a high % of the tests
- **Caution required in interpreting a given test result**

Anthropometrics Research to Develop Respirator Fit Test Panels

Ziqing Zhuang, Ph.D.

June 26, 2007

CDC Workplace Safety and Health

NIOSH

NPPTL *Research to Practice through Partnerships*

Acknowledgment

Ronald Shaffer, Ph.D.
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Lauren Stein
Latoya Williams
Alex Reddington
Dennis Groce

CDC Workplace Safety and Health   NIOSH   NPPTL *Research to Practice through Partnerships*

Importance of Test Panels

- **Anthropometric panels of facial dimensions are relied upon to provide sizing reference for respirators in many applications**

  – APF establishment

  – Respirator design and development

  – TIL certification and standards

  – Research standards

History of LANL Panels

- **No survey of facial dimensions of the U.S. civilian workers**

- **The 1967 and 1968 US Air Force anthropometric survey**

- **The facial anthropometry was assumed to be representative of U.S. adults**

- **Face length, face width, and lip length**

LANL 25-Member Panel for Full-Facepiece Respirators

Face Width (mm)

	117.5	126.5	135.5	144.5	153.5
133.5			2	2	
123.5		2	5	2	
113.5	2	4	2		
103.5	2	2			
93.5					
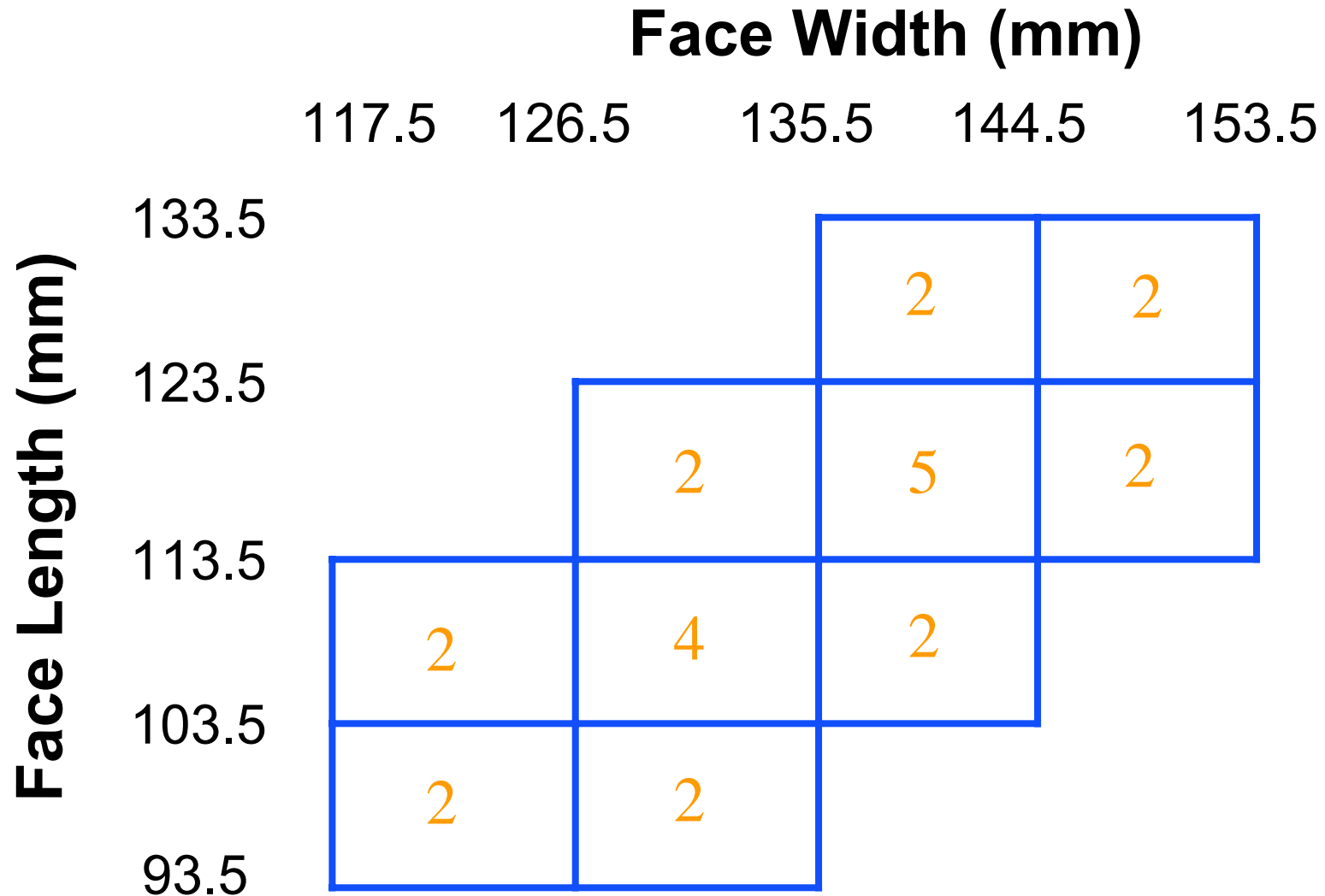
Face Length (mm)

LANL 25-Member Panel for Half-Mask Respirators

Lip Length (mm)

	34.5	43.5	52.5	61.5
133.5		2	2	
123.5	1	5	3	
113.5	3	4	1	
103.5	2	2		
93.5				

Face Length (mm)

Panel Applicability Problem

- **Concern raised:**

  - Demographics of the U.S. population has changed over the last 30 years

  - Military data may not fairly represent the diversity of face sizes

Race Distribution of 1967–1968 Air Force Survey Subjects and 2000 Census Data
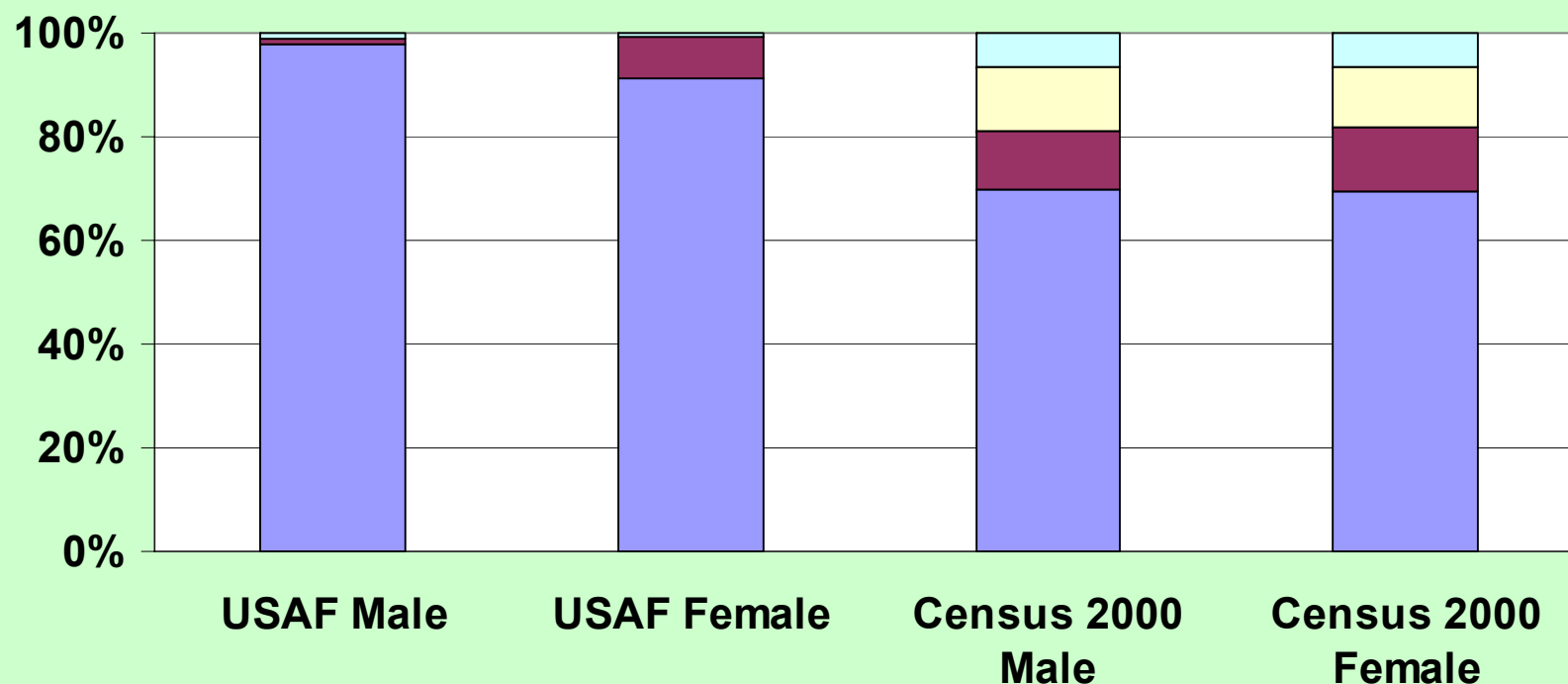
Legend: White, African American, Hispanic, Others

Categories: USAF Male, USAF Female, Census 2000 Male, Census 2000 Female

Age Distribution of 1967–1968 Air Force Survey Subjects and 2000 Census Data
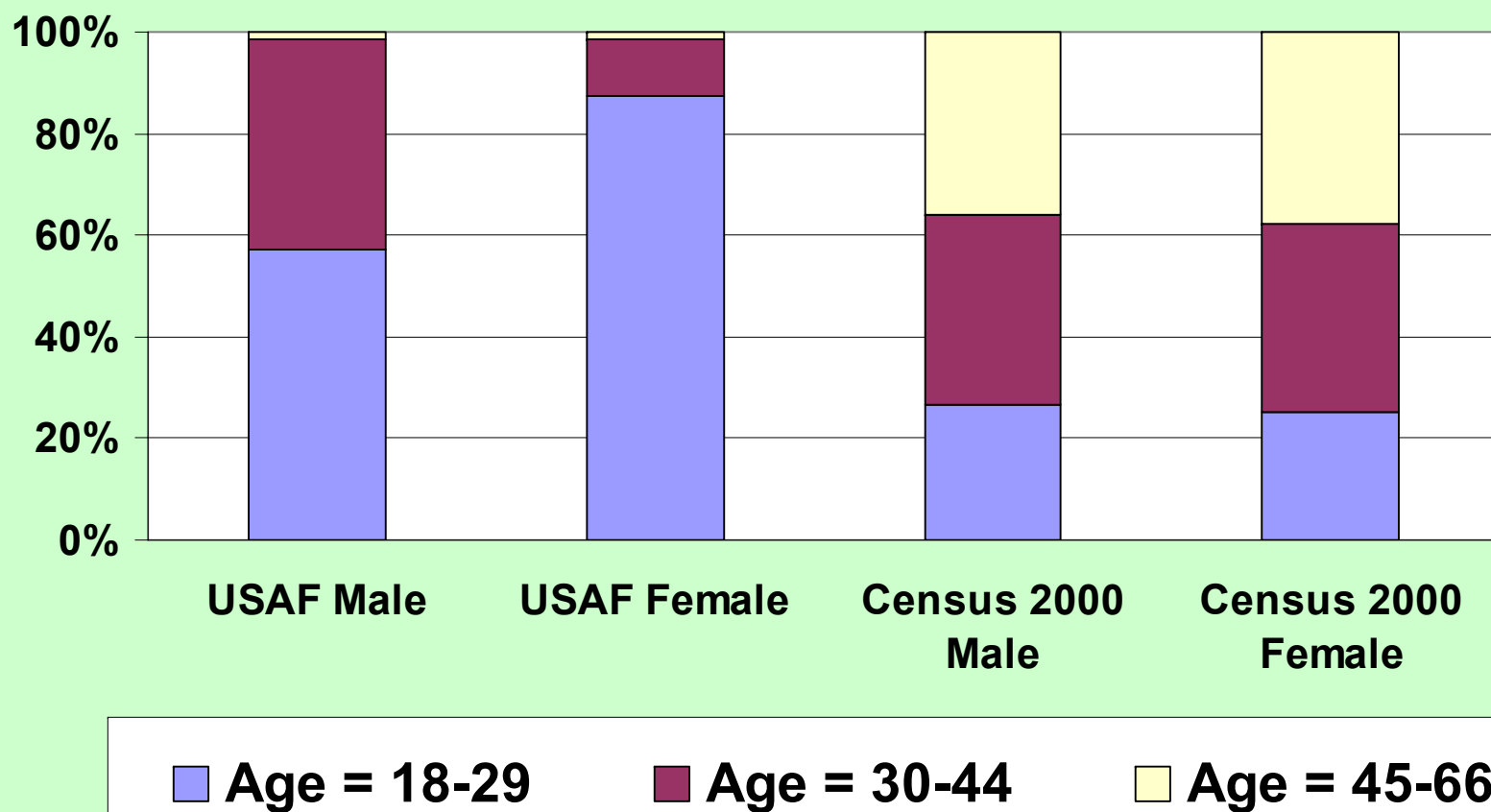
Panel Applicability Problem

- **Scientific Evidence:**

  - Leigh measured 1,467 employees (1975)

  - Bureau of Mines surveyed 48 male mine rescue workers (1978)

  - NIOSH found that 16% of Civilian American and European Surface Anthropometry Resources (CAESAR) subjects were outside the limits of the LANL panel for full-facepiece respirators (2002)

  - Lip length is not appropriate for half-masks (Oestenstad, 1990, 1992)

NIOSH Research

- Develop an anthropometric database detailing the face-size distributions of respirator users

- Evaluate the applicability of the LANL respirator fit test panels

- Investigate correlation between facial dimensions and respirator fit

- Develop new respirator fit test panels

Panel Development Timeline

- **Protocol development and review**
  - November 2002

- **Data collection**
  - September 2003

- **Data analyses & report preparation**
  - May 2004

- **First Proposed NIOSH panel**
  - August 2004

- **Peer-review**
  - January 2007

Anthropometric Survey

- A stratified sampling plan was used

  - Two-gender strata: male and female

  - Four race/ethnic groups:

    White, African American, Hispanics, and others

  - Three age groups:

    18–29, 30–44, and 45–66

- Sample size: 3,997

Traditional Measurements

Sliding Caliper

Spreading Caliper
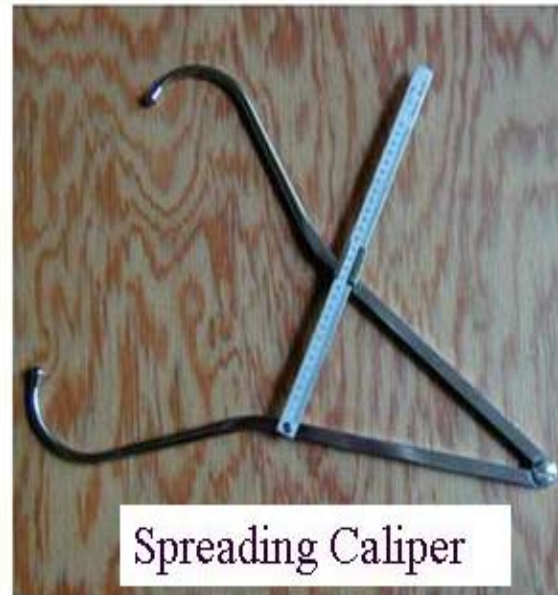
Anthropometer

Anthropometric Data Base

Race	Male Age group 18–29	Male Age group 30–44	Male Age group 45–65	Total	Female Age group 18–29	Female Age group 30–44	Female Age group 45–66	Total
White	271	611	485	1,367	151	194	174	519
African American	101	255	278	634	51	213	325	589
Hispanic	155	182	75	412	53	36	37	126
Other	24	47	59	130	52	65	103	220
Total	551	1095	897	2,543	307	508	639	1,454

CDC Workplace Safety and Health   NIOSH   NPPTL Research to Practice through Partnerships

Fitting NIOSH Data into LANL Panel

Face Width (mm)

	117.5	126.5	135.5	144.5	153.5
133.5			11.8%	10.2%	
123.5		10.6%	18.3%	11.2%	
113.5	2.1%	10.0%	9.2%		
103.5	0.4%	0.9%			
93.5					

Face Length (mm)

Total = 84.7%
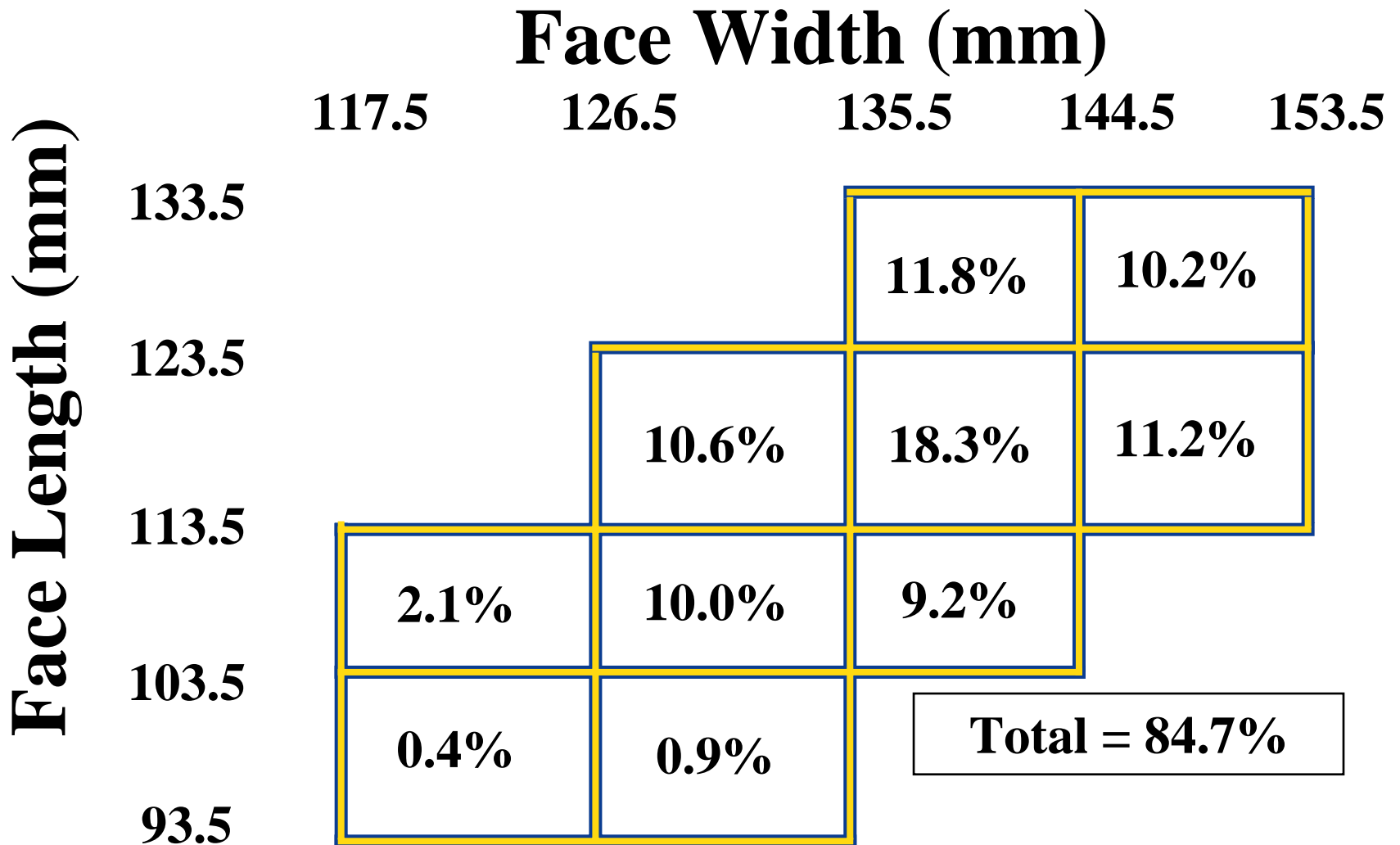
Bivariate Distribution against LANL Panel
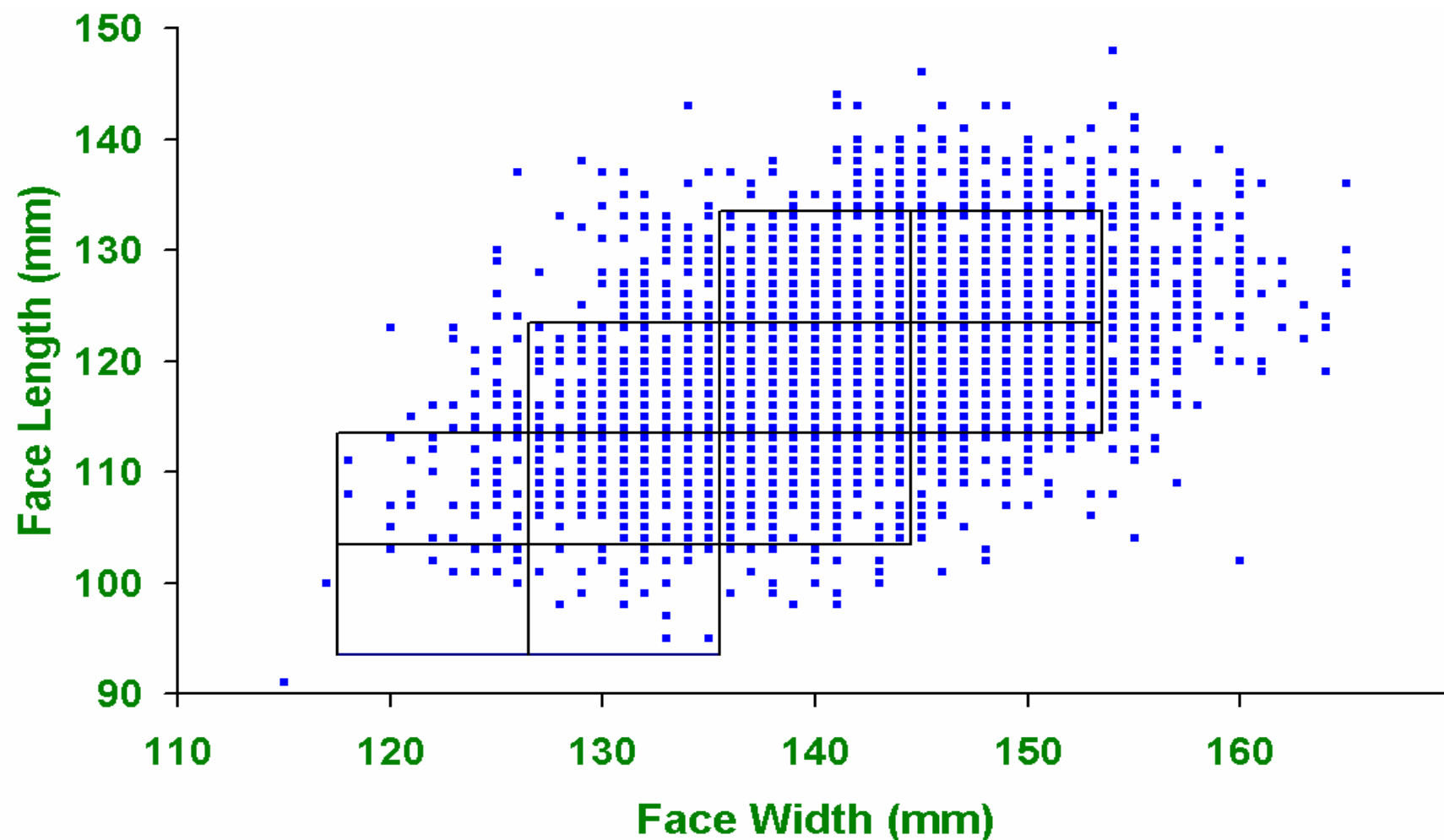
Development of New Panels

- **Two approaches:**

  – Bivariate

  – Principal component analysis

Principal Component Analysis: Theory

PCA defines a new coordinate system using linear combinations of the original variables to describe trends in the data
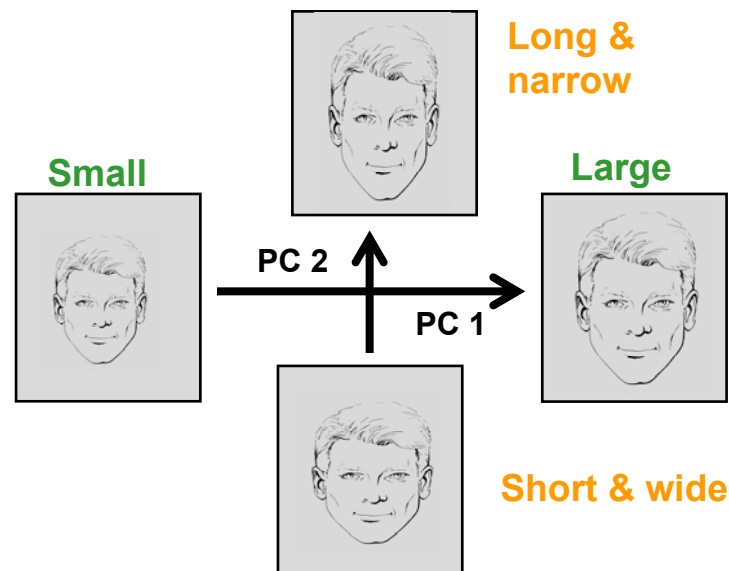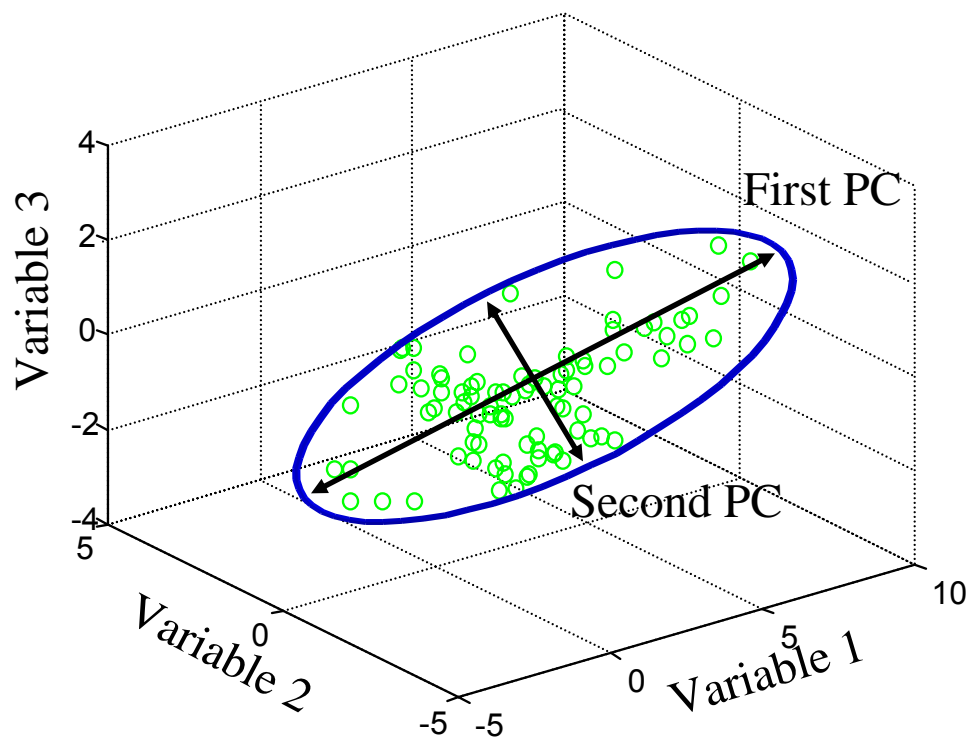
Criteria for Selecting Dimensions

- **The dimensions are relevant to respirator fit**
  - Literature review
  - Expert opinion
- **The dimensions excluded can be predicted by the dimensions included in the PCA**
- **The number of dimensions is reasonable**
- **Dimensions that are difficult to measure and/or highly variable are excluded**

NIOSH Bivariate Panel

- 10-cell panel

- 25 subjects

- The number of subjects can be adjusted

- At least two subjects for each cell

- Matching the distribution of the population

- Face length and face width were selected to define the bivariate panel for both half-masks and full-facepiece respirators
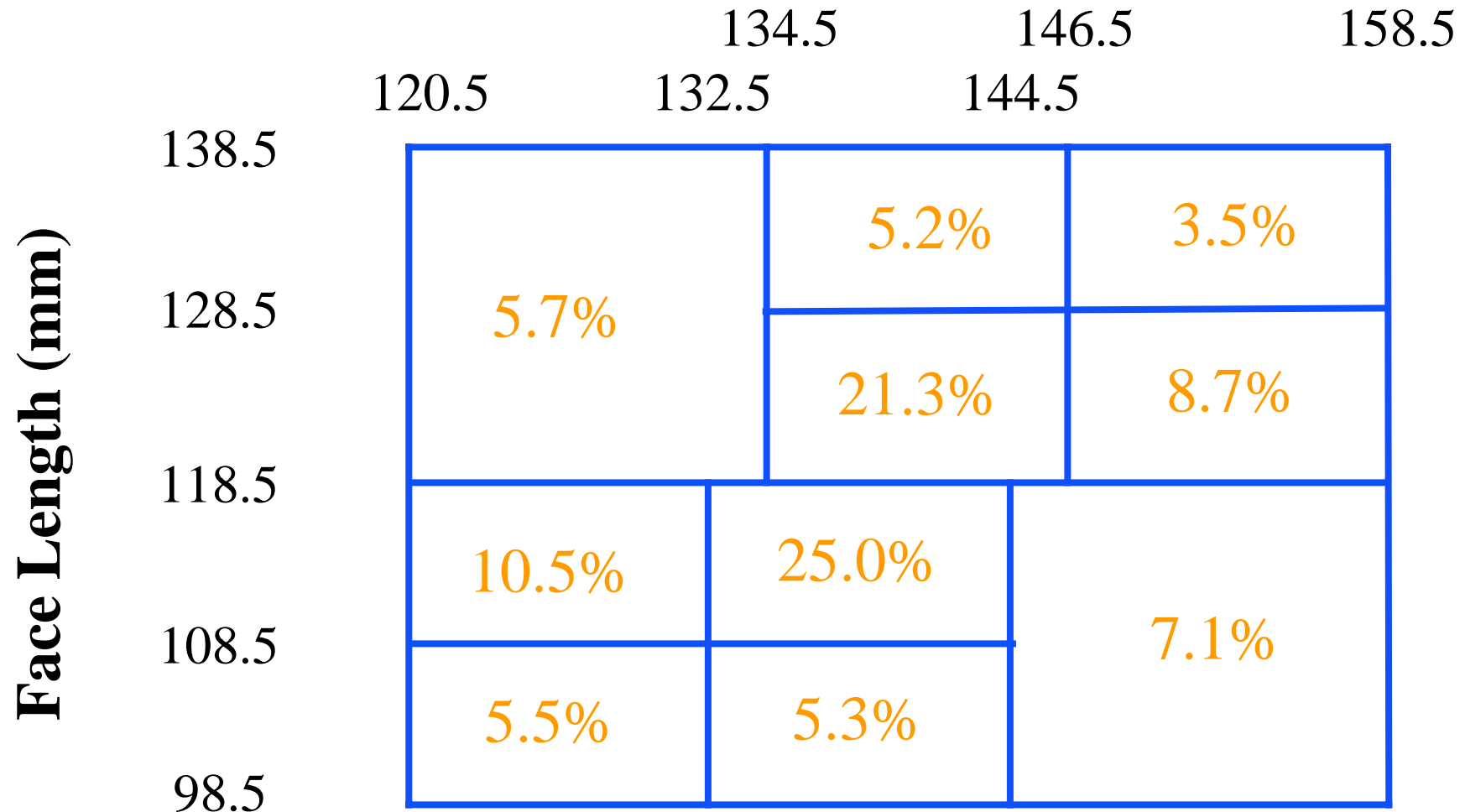
NIOSH Bivariate Panel
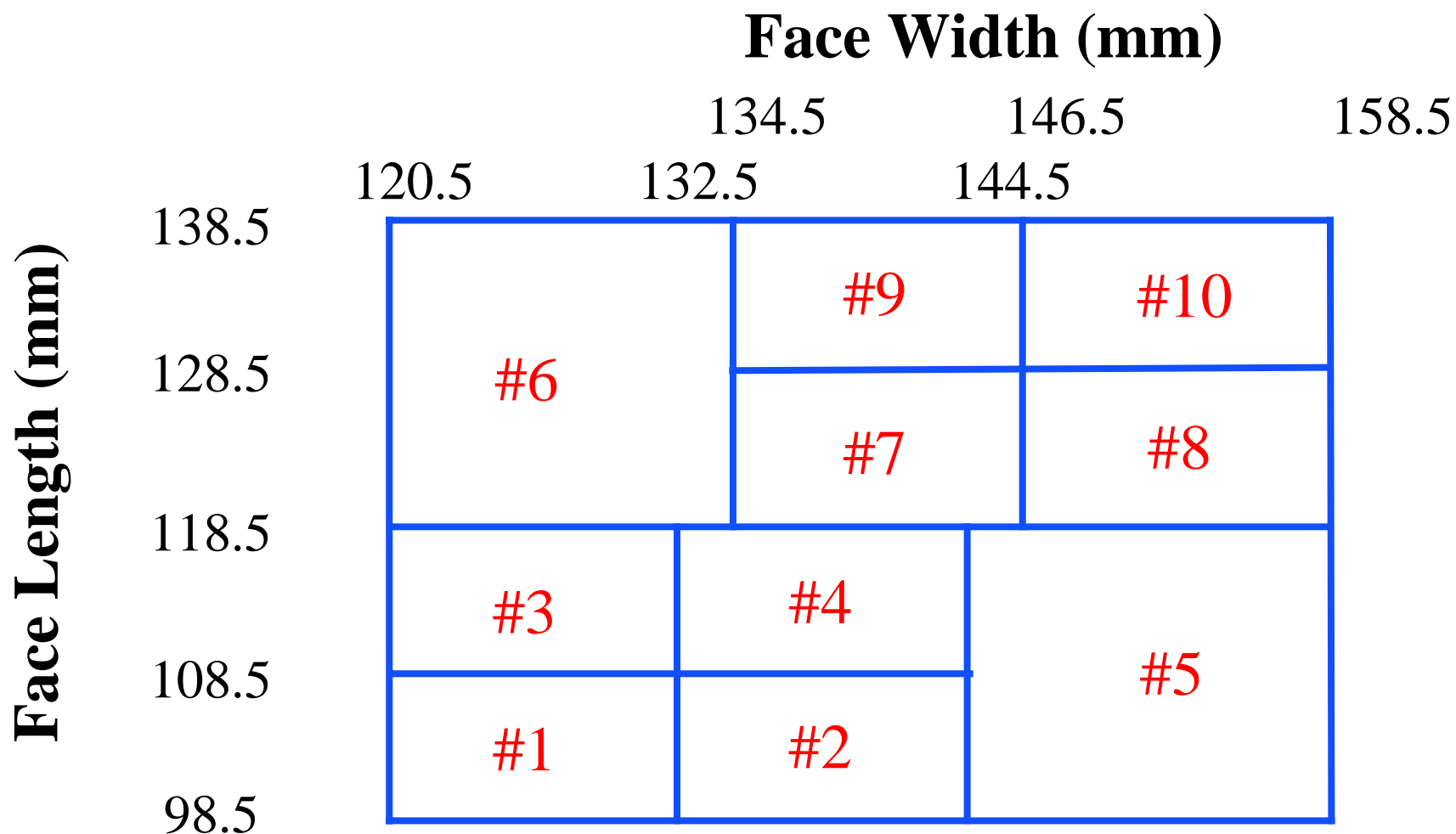
Scatter Plot against NIOSH & LANL Panels
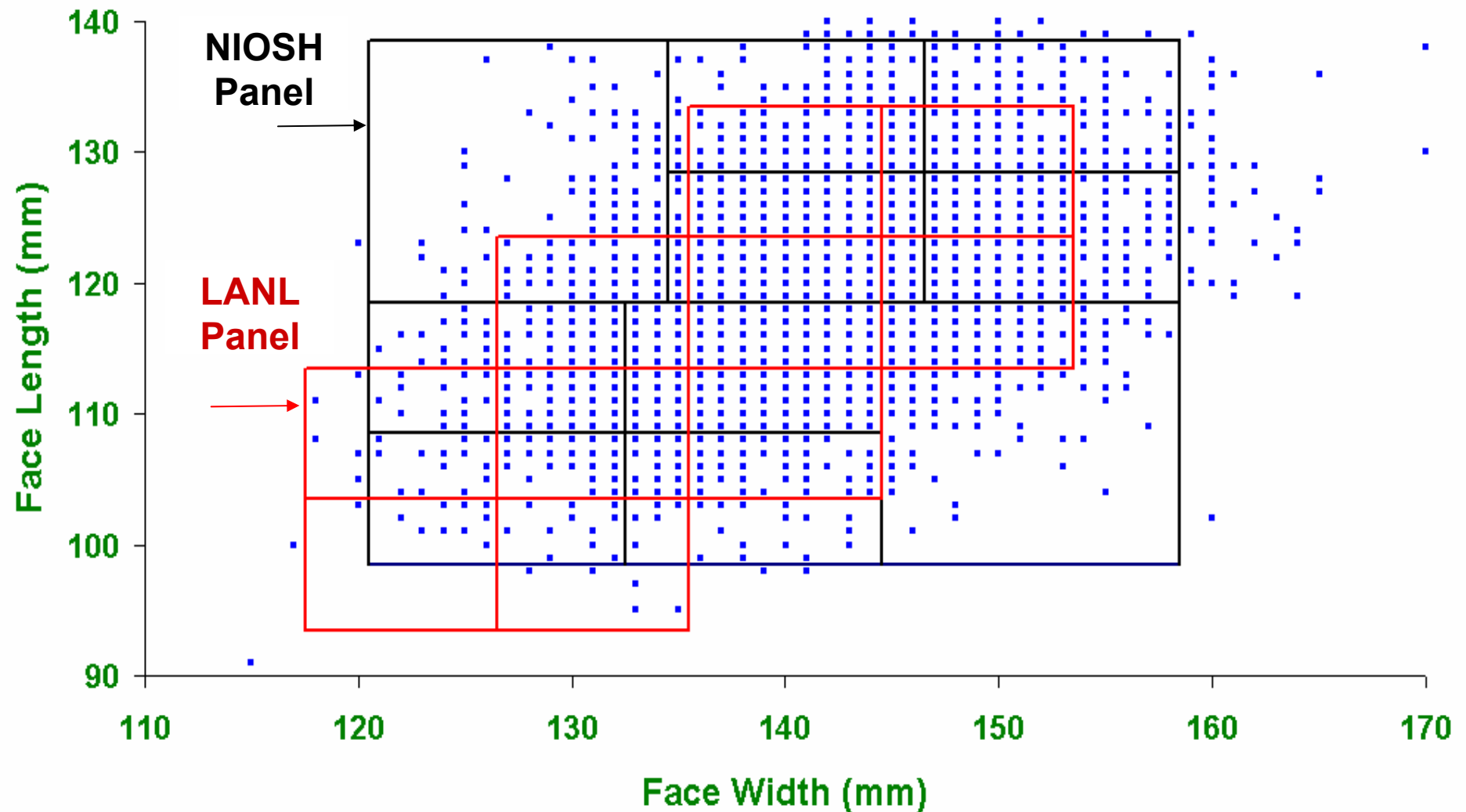
Distribution of US Workers by NIOSH Panel
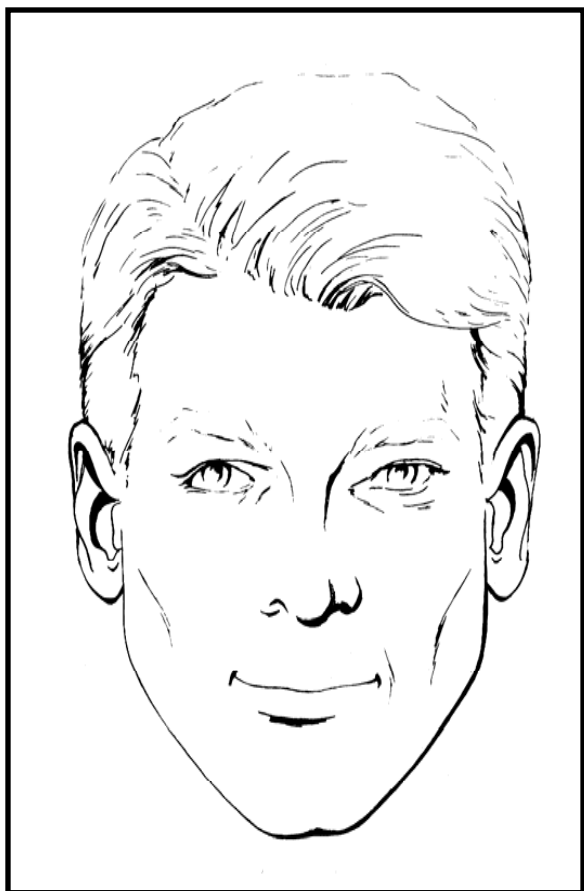
25-Member Panel

Face Width (mm)

Dimensions Used in the PCA Panel

Minimum Frontal Breadth

Face Width

Bigonial Breadth

Face Length

Interpupillary Breadth

Head Breadth

Nose Protrusion

Nose Breadth

Nasal Root Breadth

Subnasale-Sellion Length

Principal Component Analysis
(Males and Females)

Variables	Eigenvectors	
	PC 1 (42%)	PC 2 (16%)
Minimum Frontal Breadth	0.3433	-0.1530
Face Width	0.4265	-0.0391
Bigonial Breadth	0.3727	-0.0933
Face Length	0.3296	0.3598
Interpupillary Breadth	0.3635	-0.1731
Head Breadth	0.3722	0.0133
Nose Protrusion	0.1136	0.5518
Nose Breadth	0.3011	-0.2108
Nasal Root Breadth	0.2023	-0.3412
Subnasale-Sellion Length	0.1937	0.5843

NIOSH PCA Panel
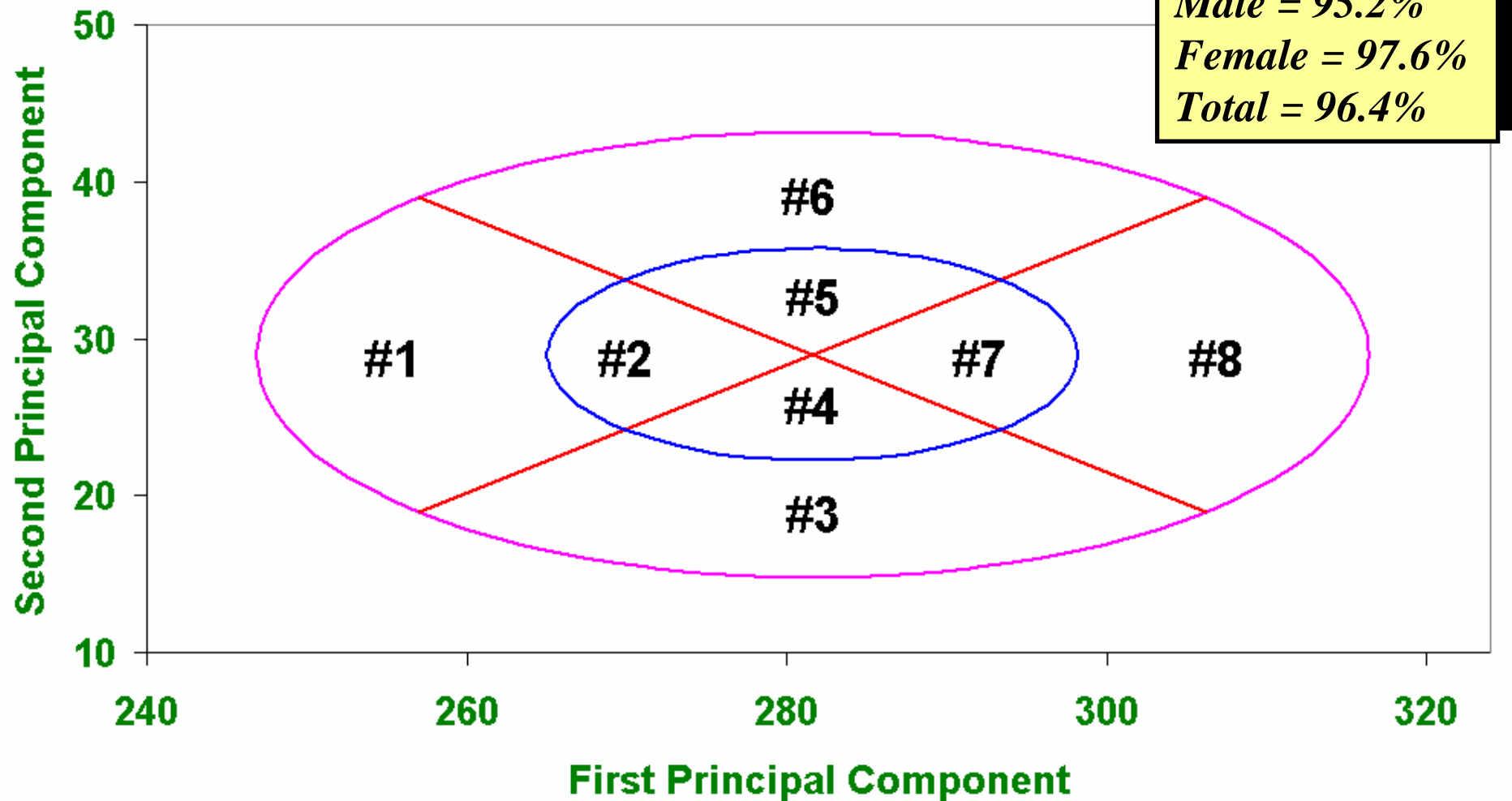
Facial Shape Trends

Long/Narrow Nose

Long Face

Shape

Short Face
Short/Wide Nose
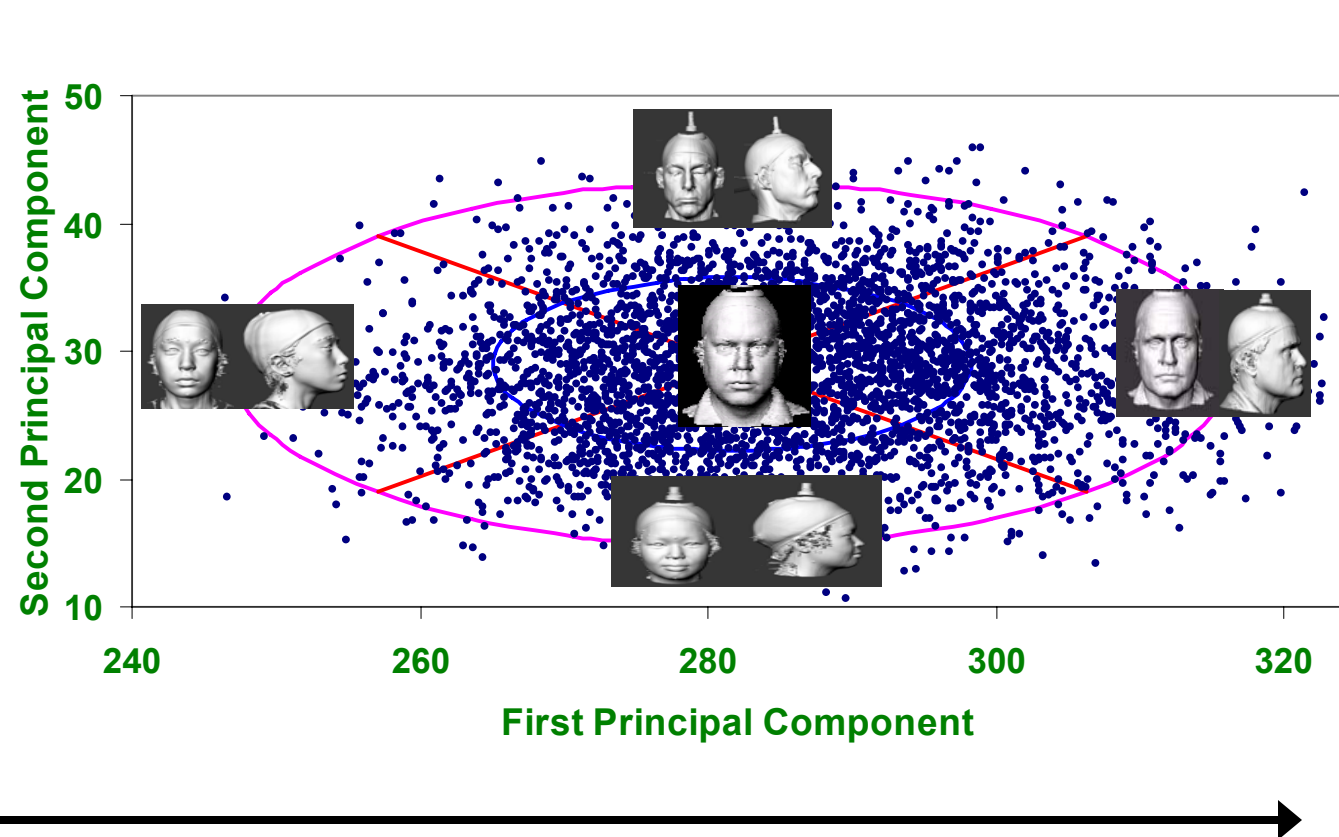
Small   Overall Size   Large

Second Principal Component

First Principal Component

50
40
30
20
10

240   260   280   300   320

Distribution of U.S. Workers by the PCA Panel

Cell	Male (%)	Female (%)	Total (%)
1	1.1	22.0	11.6
2	5.7	21.6	13.7
3	5.6	17.8	11.7
4	9.1	15.5	12.3
5	16.7	8.1	12.4
6	17.9	6.6	12.2
7	18.4	5.1	11.7
8	20.8	1.0	10.8
Total	95.2	97.6	96.4

25-Member PCA Panel

Cell	Male	Female	Total
1	0	3	3
2	1	3	4
3	1	2	3
4	1	2	3
5	2	1	3
6	2	1	3
7	2	1	3
8	3	0	3
Total	13	12	25

Conclusions

- **Two panels were developed**

- **Respirators designed to fit these panels are expected to accommodate more than 95% of the current U.S. civilian workforce**

- **Both panels represent an improvement over the LANL panels used today**

- **Training video on facial measurement and computer program are available upon request**

Journal Publications

1. Zhuang Z, Guan J, Hsiao H, and Bradtmiller B [2004]. Evaluating the Representativeness of the LANL Respirator Fit Test Panels for the Current U.S. Civilian Workers. Journal of the International Society for Respiratory Protection, 21(III-IV):83-93.

2. Zhuang Z and Bradtmiller B [2005]. Head-and-Face Anthropometric Survey of U.S. Respirator Users. J Occup. Environ. Hyg., 2, 567-577.

3. Zhuang Z, Coffey CC, and Berry Ann R [2005]. The effect of subject characteristics and respirator features on respirator fit. J Occup. Environ. Hyg. 2, 641-649.

4. Roberge R, Zhuang Z, Stein, L [2006] Association of Body Mass Index with Facial Dimensions for Defining Respirator Fit Panels. Journal of the International Society for Respiratory Protection, 23(I-II):44-52.

5. Zhuang Z, Bradtmiller B, and Shaffer RE [2007]. New Respirator Fit Test Panels Representing the Current U.S. Civilian Workforce. Journal of Occupational and Environmental Hygiene (In press).

6. Zhuang Z, Roberge R, Landsittel D, Stein L, Viscusi DJ and Shaffer RE [2007]. Facial anthropometric differences among race/age groups. In preparation to submit to the Annals of Occupational Hygiene.

New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force

Ziqing Zhuang,[1] Bruce Bradtmiller,[2] and Ronald E. Shaffer[1]

[1]National Institute for Occupational Safety and Health, National Personal Protective Technology
Laboratory, Pittsburgh, Pennsylvania
[2]Anthrotech, Yellow Springs, Ohio

The fit test panels currently used for respirator research, design, and certification are 25-subject panels developed by Los Alamos National Laboratory (LANL) and are based on data from the 1967 and 1968 anthropometric surveys of U.S. Air Force personnel. Military data do not represent the great diversity in face size and shape seen in civilian populations. In addition, the demographics of the U.S. population have changed over the last 30 years. Thus, it is necessary to assess and refine the LANL fit test panels. This paper presents the development of new respirator fit test panels representative of current U.S. civilian workers based on an anthropometric survey of 3997 respirator users conducted in 2003. One panel was developed using face length and face width (bivariate approach) and weighting subjects to match the age and race distribution of the U.S. population as determined from the

INTRODUCTION

In the early 1970s, the Respirator Research and Development Section of the Los Alamos National Laboratory (LANL) was asked by the National Institute for Occupational Safety and Health (NIOSH) to develop anthropometric specifications for fit testing full- and half-facepiece respirators. Because no survey of face dimensions of the U.S. workers was available at that time, the LANL team decided to develop these specifications based on the 1967 and 1968 U.S. Air Force (USAF) anthropometric surveys.[1-2]

Prompted by concerns over the possible inapplicability of military data to civilian workers, the Los Alamos team sur-

Presentations

1. Zhuang Z, Coffey C, BerryAnn R, Lawrence RB, Viscusi D, The effect of subject characteristics and respirator features on respirator fit, American Industrial Hygiene Association Conference & Expo, Dallas, TX May 10-15, 2003.

2. Zhuang, et al. "Anthropometric Survey of Respirator Users" at the 2004 American Industrial Hygiene Conference and Exposition (AIHCE), Atlanta, Georgia, May 10, 2004.

3. Zhuang, et al. "Evaluating the Representativeness of the LANL Respirator Fit Test Panels for the Current U.S. Civilian Workers" at the ISRP 12th International Conference, Yokohama, Japan, November 9-12, 2004.

4. Zhuang, et al. "New Respirator Fit Test Panels Representing the Current U.S. Civilian Workforce" at the ISRP 12th International Conference, Yokohama, Japan, November 9-12, 2004.

5. Zhuang Z, Williams LM, Viscusi DJ and Shaffer RE. Facial anthropometric differences among race/age groups. American Industrial Hygiene Conference and Exposition, Anaheim, CA, May 18-26, 2005.

6. Roberge, R., Zhuang Z., Stein, L., Association of Body Mass Index with Facial Dimensions for Defining Respirator Fit Panels. American Industrial Hygiene Conference and Exposition, Chicago, IL, May 14-16, 2006.

7. Z. Zhuang, B. Bradtmiller, and R.E. Shaffer, New Respirator Fit Test Panel Based on Principal Component Analysis. American Industrial Hygiene Conference and Exposition, Chicago, IL, May 14-16, 2006.

8. Zhuang Z, Viscusi D, and Reddington A. "Anthropometrics for developing headforms for testing respiratory and eye protective devices" at the ISRP 13th International Conference, Toronto, Canada, Aug 27- Sep 1, 2006.

9. Chen W, Zhuang Z, et al. "Head-and-face Anthropometric Survey of Chinese Respirator Users" at the 2007 American Industrial Hygiene Conference and Exposition (AIHCE), Philadelphia, PA, June 7, 2007.

Jonathan Szalajda
Chief Policy and
Standards Branch

June 26, 2007

- **Presentations posted to web site / notification via email and letter**

- **30 days for comment after posting (technical and administrative aspects)**

- **Contact Policy and Standards Development Branch for individual discussions**

- **Prepare for rulemaking**

Total Inward Leakage Program

- ## **Proposed Criteria**
    - Uses the NRFTP

    - Based on Manufacturers' User Instructions for sizing

    - TIL $\leq$ 5%

    - 26 out of 35 Test Subjects

    - Applicable to all Subpart K Half-mask respirators

    - Implementation 30 days with 3 years grandfathering

Docket Information

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  - **Robert A. Taft Laboratories, M/S C 34**
    - **TIL - NIOSH 036**
  - **4676 Columbia Parkway**
  - **Cincinnati, OH 45226**
- **Email: niocindocket@cdc.gov**
- **Fax: (513) 533-8285**
- **Phone: (513) 533-8303**
- **NPPTL Web Site: http://www.cdc.gov/niosh/npptl**

National Academies Involvement in Personal Protective Technology Activities

Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users

Les Boord, Director
Presenting for
Dr. Maryann D'Alessandro
Associate Director for Science

Research To Practice (r2p)

- **Total Inward Leakage (TIL) = r2p In Action**

- **TIL Combines:**

  – Respirator Anthropometrics Research

  – Respirator Benchmark Testing

  – Development of a Respirator Performance Requirement

  – Implementation in Respirator Certification

- **Quality of Research Achieved Through Scientific Review / Evaluation**

NPPTL Tactical Priorities

- **Science Center of Excellence**

  Improve the quality, consistency, and dependability of the science delivered to our customers and stakeholders through a program of rigorous evaluation.

- **Strategically Plan for Evaluation Activities**

  Allocate 3% to 8% of NPPTL base budget for evaluation activities.

National Academies Involvement in NPPTL

- *Committee on PPE for the Workforce (COPPE)*
  - Three open meetings in FY06
  - Meeting 1 FY07:   Oct 23-24, 2006
  - Workshop: Feb 22, 2007 – **PPE during an Influenza Pandemic: Research, Standards, Certification and Testing Directions**

- *Review of Anthropometrics Survey and Respirator Panel Modifications*
  - Three open meetings in FY06
  - Final report received Jan 2007, Briefing Jan 22, 2007
  - Jan – Mar 2006 *- Support to HHS for Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic*

- *Review of BLS Survey of Respirator Use*
  - Three open meetings in FY06
  - Final report received Dec 2006, Briefing Feb 2, 2007

- *National Academies Evaluation of Personal Protective Technology (PPT) Cross Sector*
  - Evidence package to National Academies Aug 2007
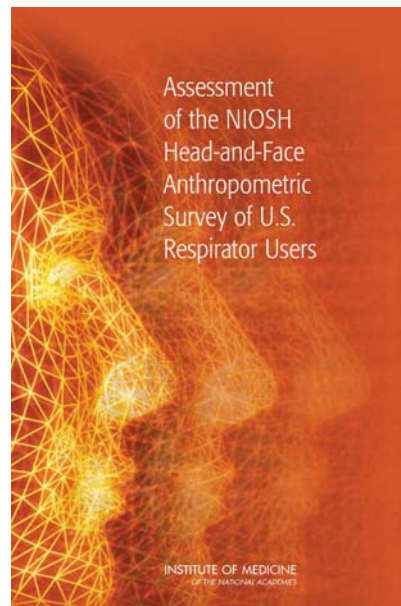 - National Academies evaluation Sept 2007
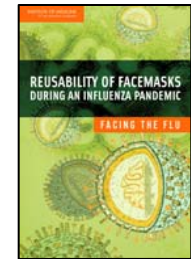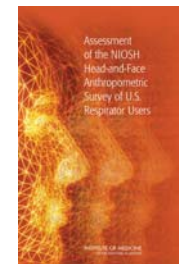
IOM Report on

Assessment of the NIOSH Head and Face Anthropometric Survey of U.S. Respirator Users

Report available at:
http://iom.edu/CMS/3740/29900.aspx

Review of Anthropometrics Survey and Respirator Panel Modifications

- **Dr. Andy Pope - National Academy Review & Report**

- **Dr. Ron Shaffer – NIOSH / NPPTL Report Action Plan**

William Newcomb
Physical Scientist

June 26, 2007

Total Inward Leakage Program
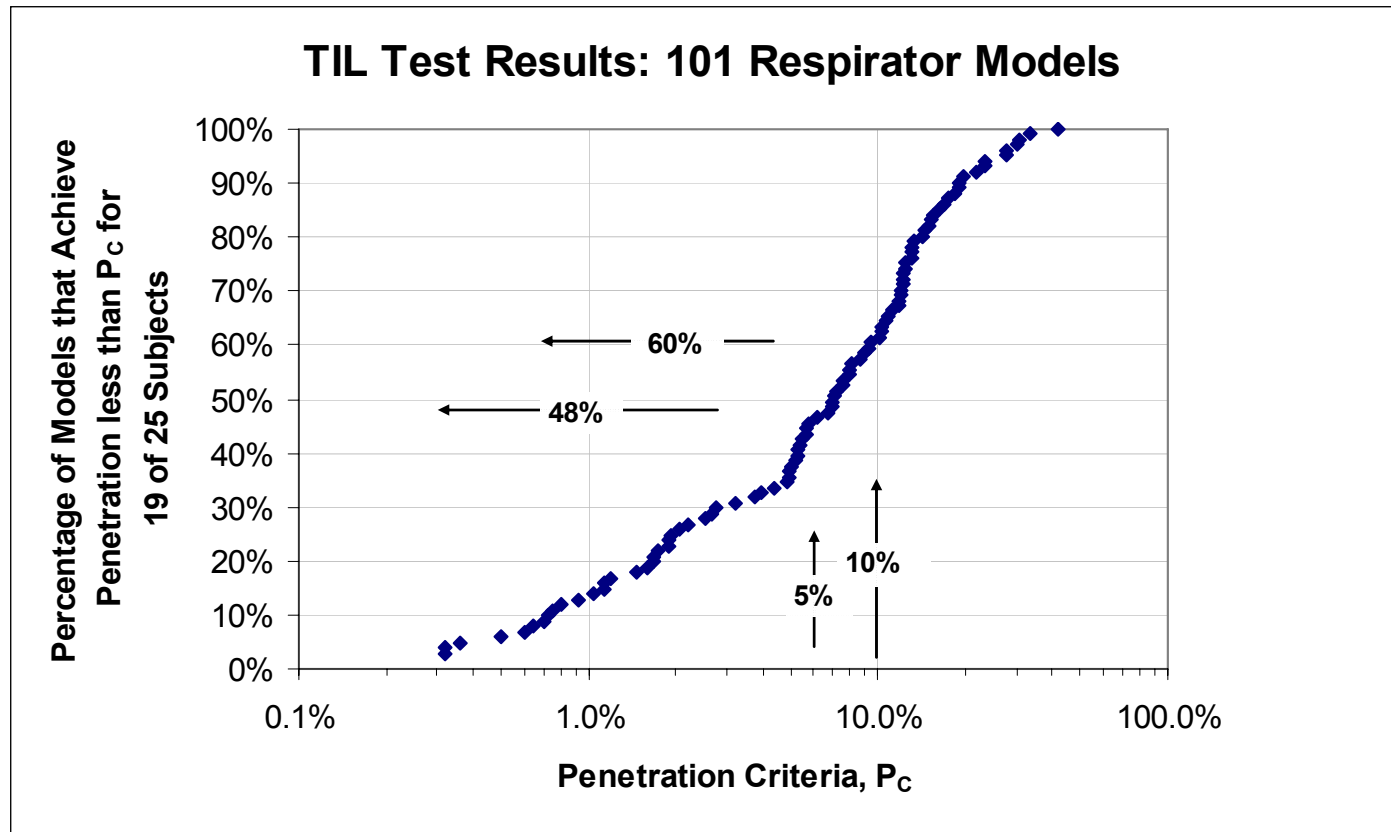
Benchmark Tests

- 57 Filtering Facepiece Respirators

- 43 Elastomeric Half-Mask Respirators

- 1 Quarter-Mask Respirator

- Entire panel of 25 Subjects per model

- Three donnings per respirator per subject

- 8250 Fit Factor data points

Total Inward Leakage Program

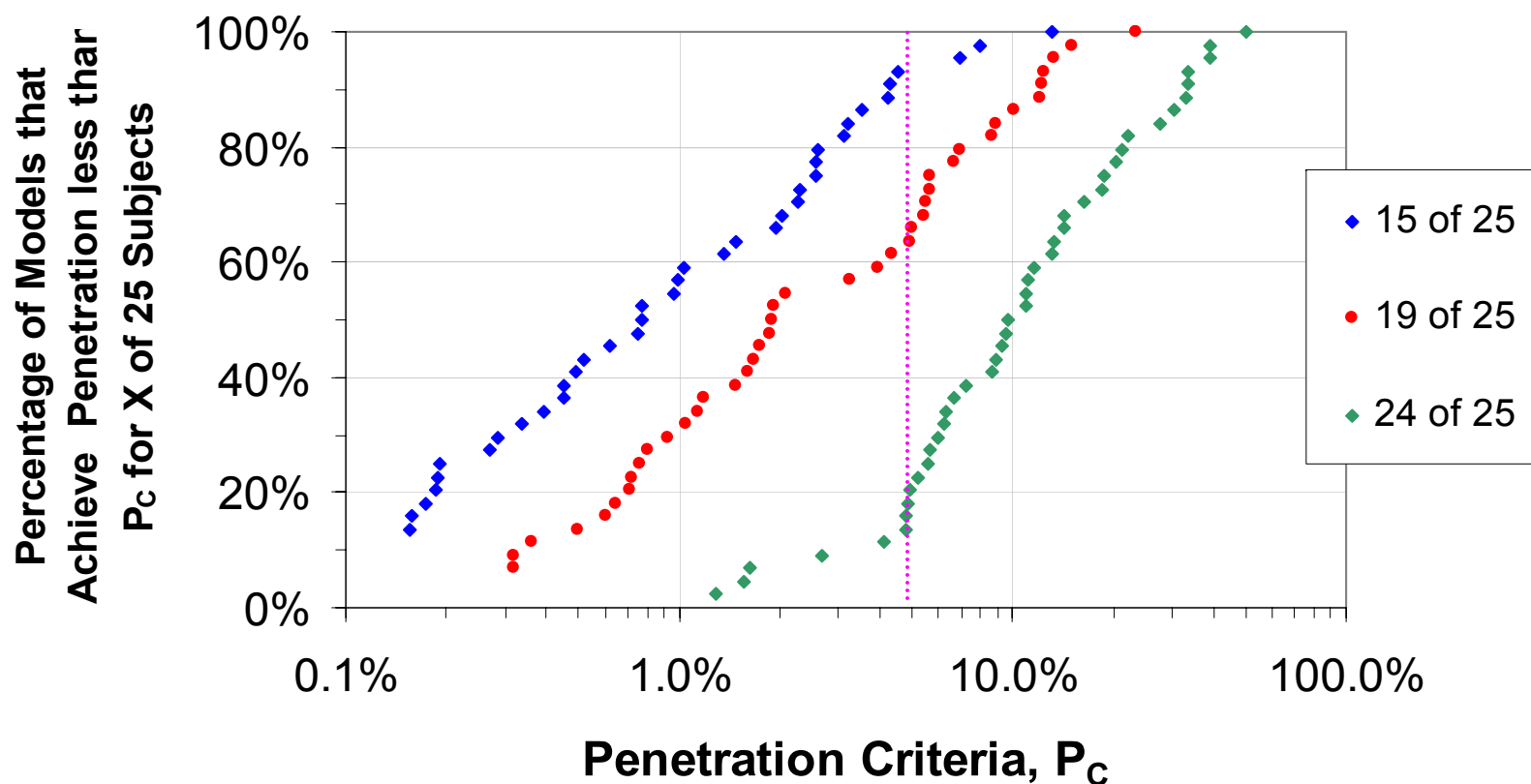$$TIL = {100} \Big/ {FF}$$

Total Inward Leakage Program

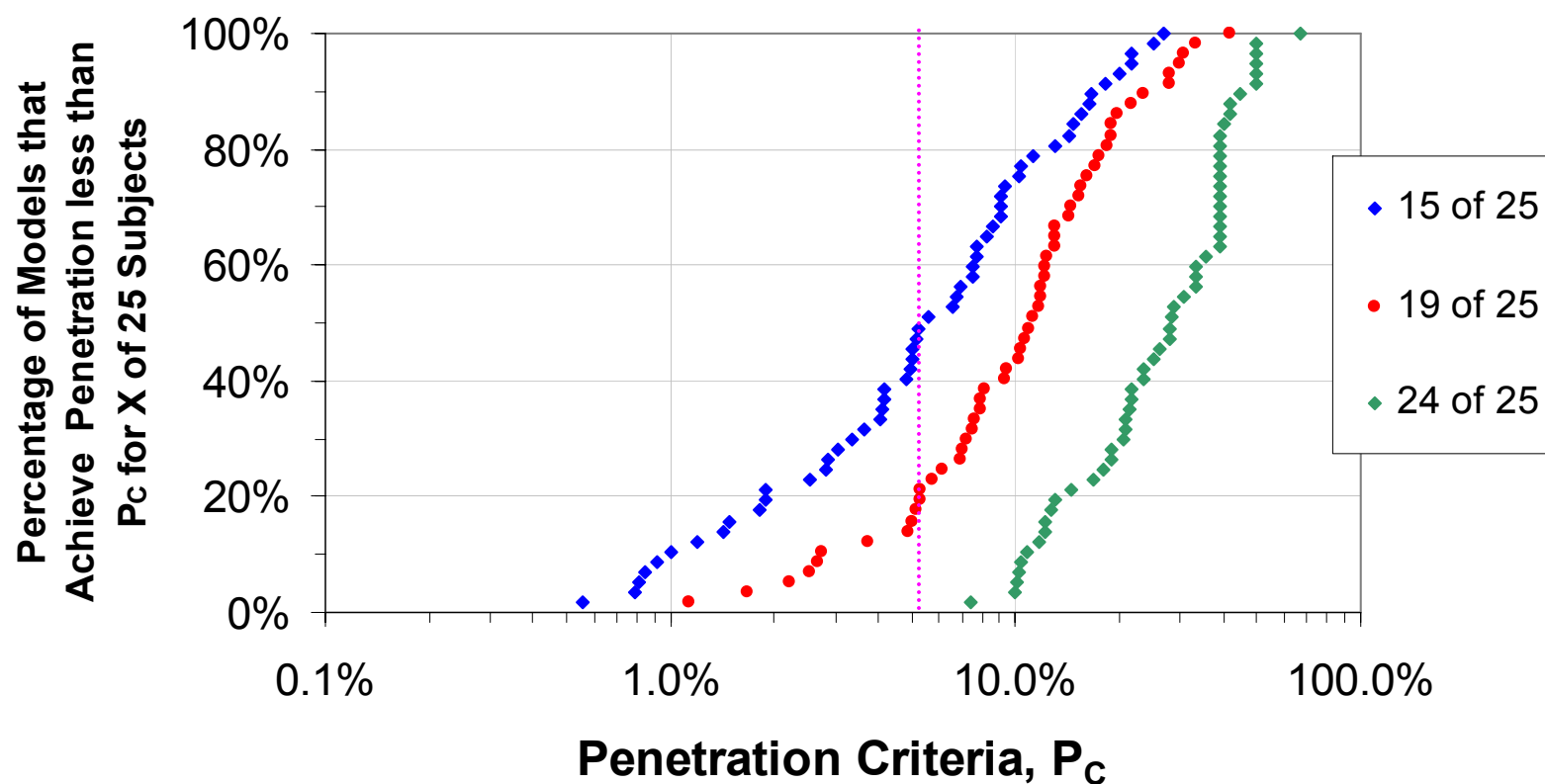TIL Test Results: 101 Respirator Models

Percentage of Models that Achieve Penetration less than P_C for 19 of 25 Subjects

60%
48%
10%
5%

Penetration Criteria, P_C

PF=1000   PF=100   PF=10   PF=1

Total Inward Leakage Program

TIL Test Results: Elastomeric Models

Percentage of Models that Achieve Penetration less than P_c for X of 25 Subjects

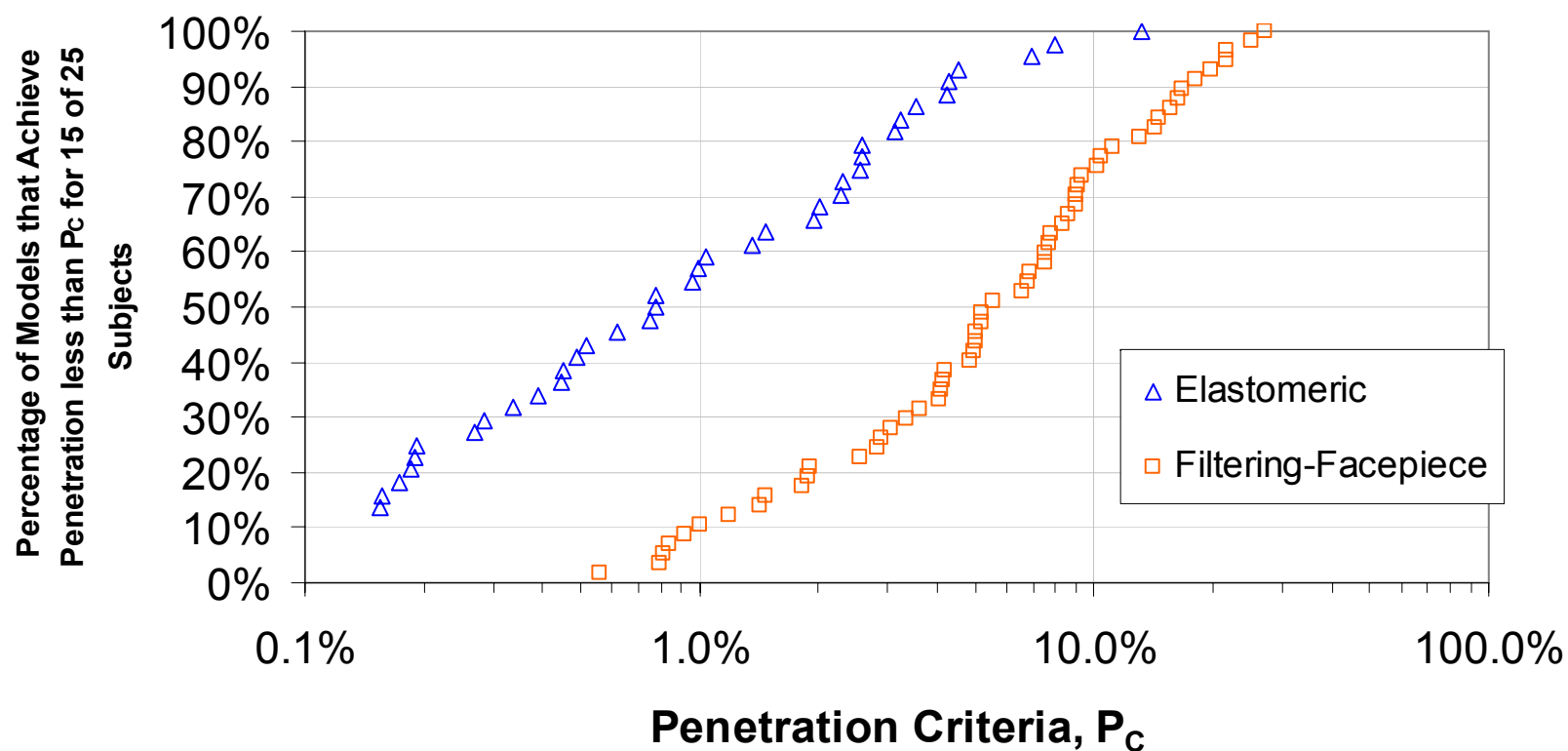Penetration Criteria, P_C

- 15 of 25
- 19 of 25
- 24 of 25

Total Inward Leakage Program
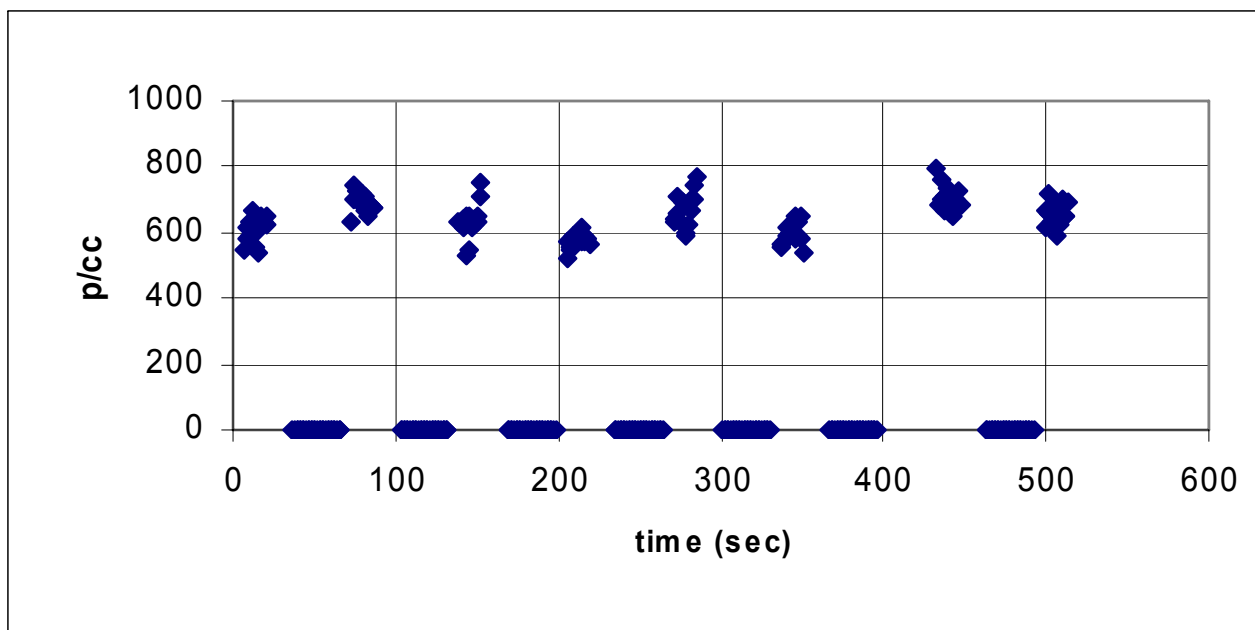

TIL Test Results: Filtering-Facepiece Models

Total Inward Leakage Program

TIL Test Results: Elastomeric vs. Filtering Facepiece

Total Inward Leakage Program

Summary of Results:
For the small-sized FFP models, the mean penetration value (across all subjects within a

Total Inward Leakage Program

To correct this switching error, the second ambient measurement was used to replace the first

Total Inward Leakage Program

To correct this switching error, the fit factor was calculated without the last in-mask (normal breathing) sample

Total Inward Leakage Program

To correct this switching error, the prior and subsequent ambient measurements were used to replace the averages
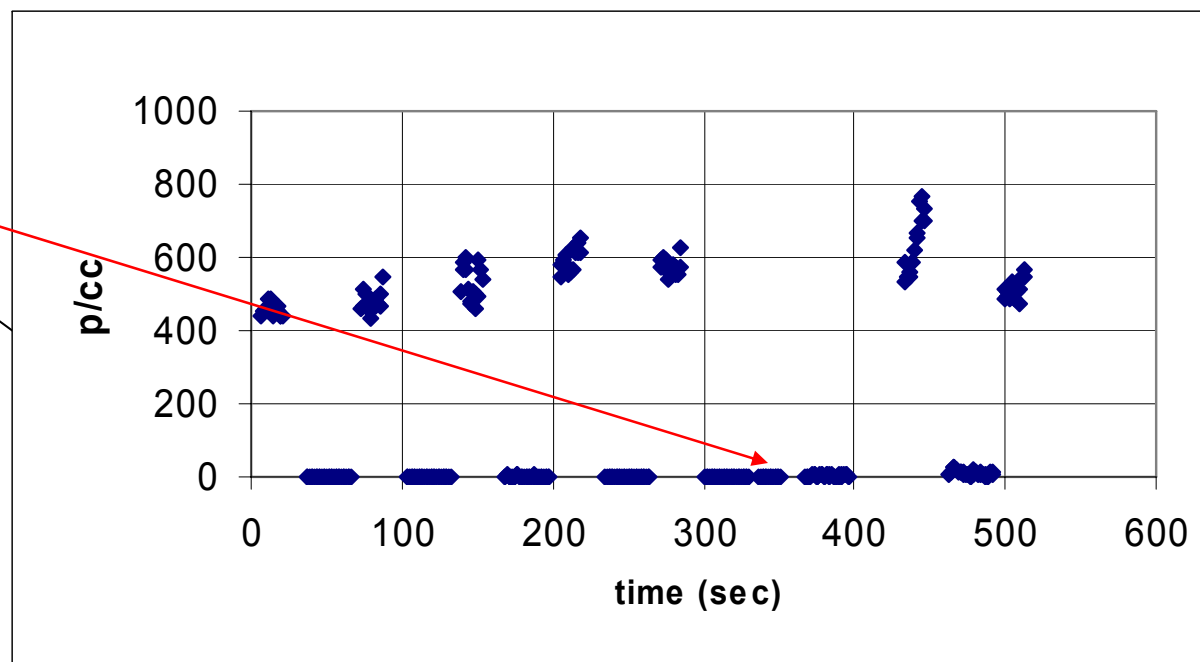
Total Inward Leakage Program

Table 1. Small-Sized Models by Cells of the NPPTL Panel
mean penetration (sample size)
[minimum, maximum]
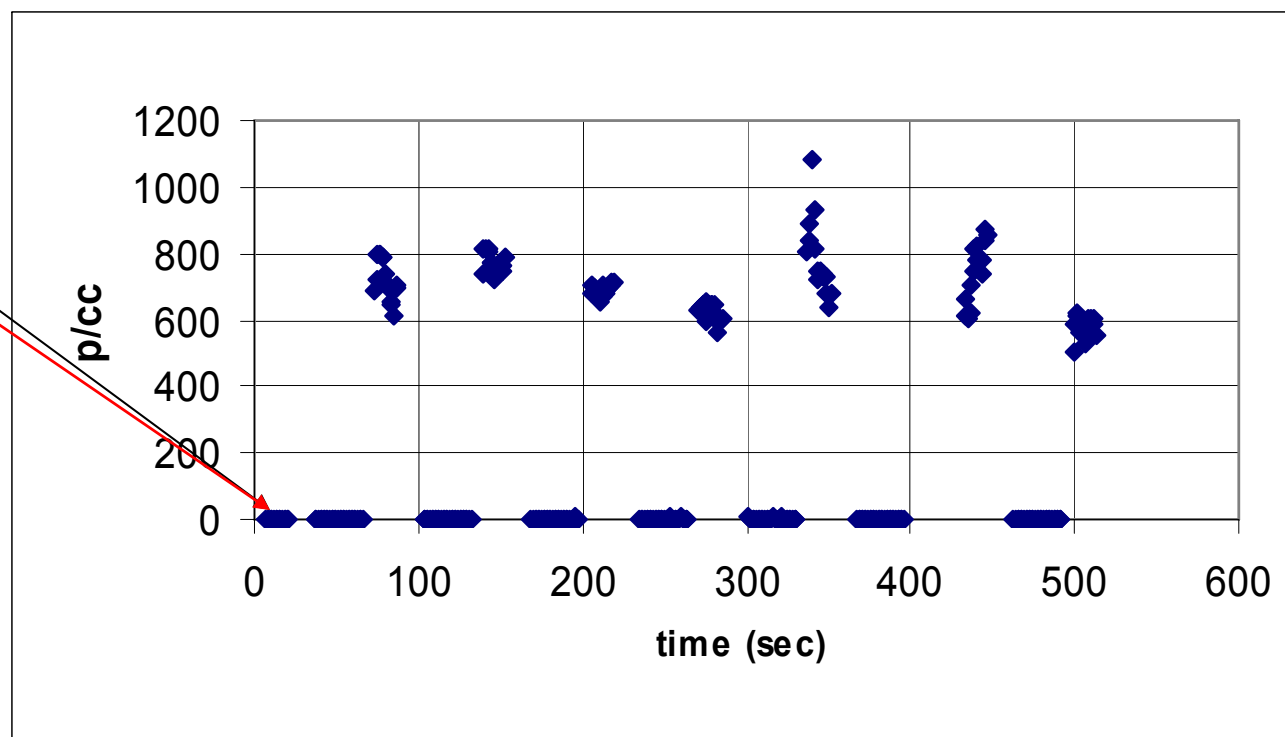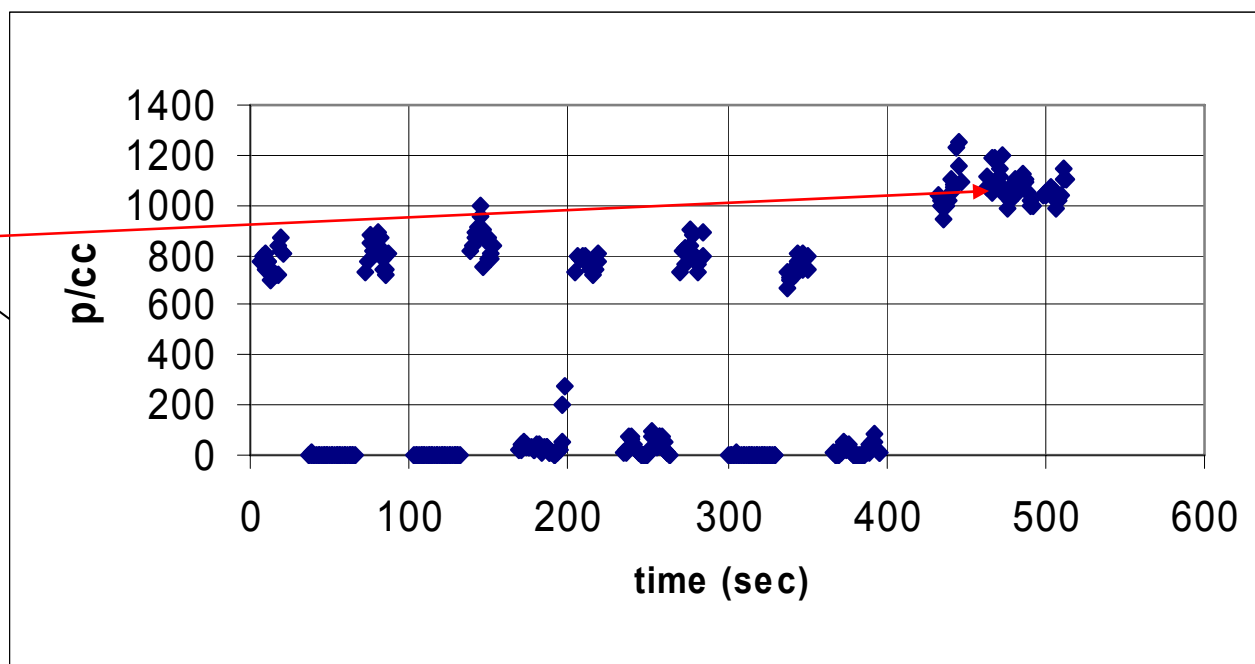cumulative percent below 1% penetration; below 5%; below 10%
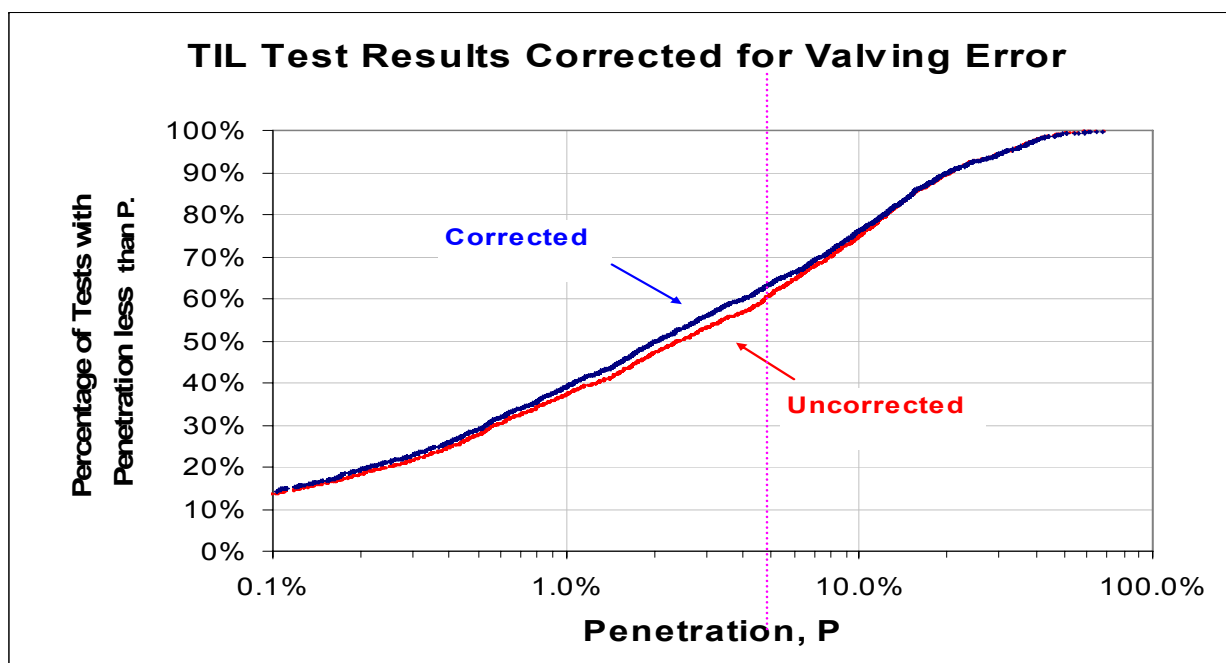
Summary of Results:
For the small-sized FFP models, the mean penetration value (across all subjects within a

Total Inward Leakage Program

- ## Summary of Data Review

  – Data was corrected where applicable

  – Uncorrectable data not used

  – Corrections did not significantly change the results

Total Inward Leakage Program

Data Availability

- – Data will be made available to those Manufacturers who wish to review their data

Total Inward Leakage Program

- ## Summary of TIL Benchmark Results

    - A wide variation exists between the overall fitting characteristics of half-mask respirators

    - Statistical difference was observed between elastomeric half-mask TIL and filtering facepiece TIL, but there is overlap

- ## Conclusion

    - A TIL performance requirement as part of respirator certification is necessary

    - With the tested respirators, it should be easier for a potential wearer to obtain the OSHA required Fit Factor during a fit test with an elastomeric half-mask than with a filtering facepiece

William Newcomb
Physical Scientist

June 26, 2007

Total Inward Leakage Program

- ## **Technical Concepts**
  - – Proposed Requirements
  - – Test subjects
  - – Test protocol
  - – Applicability/Schedule

Total Inward Leakage Program

- ## **Proposed Requirements**
  - Uses the NRFTP
  - Based on Manufacturers' User Instructions for sizing
  - TIL $\leq$ 5%
  - 26 out of 35 Test Subjects
  - Applicable to all Subpart K Half-mask respirators

Process for Subject Selection

Measure 10 facial dimensions

↓

Classify subjects by the PCA Panel

↓

Outliers? → **Yes** Do Not Use

↓

Classify subjects by the NRFTP
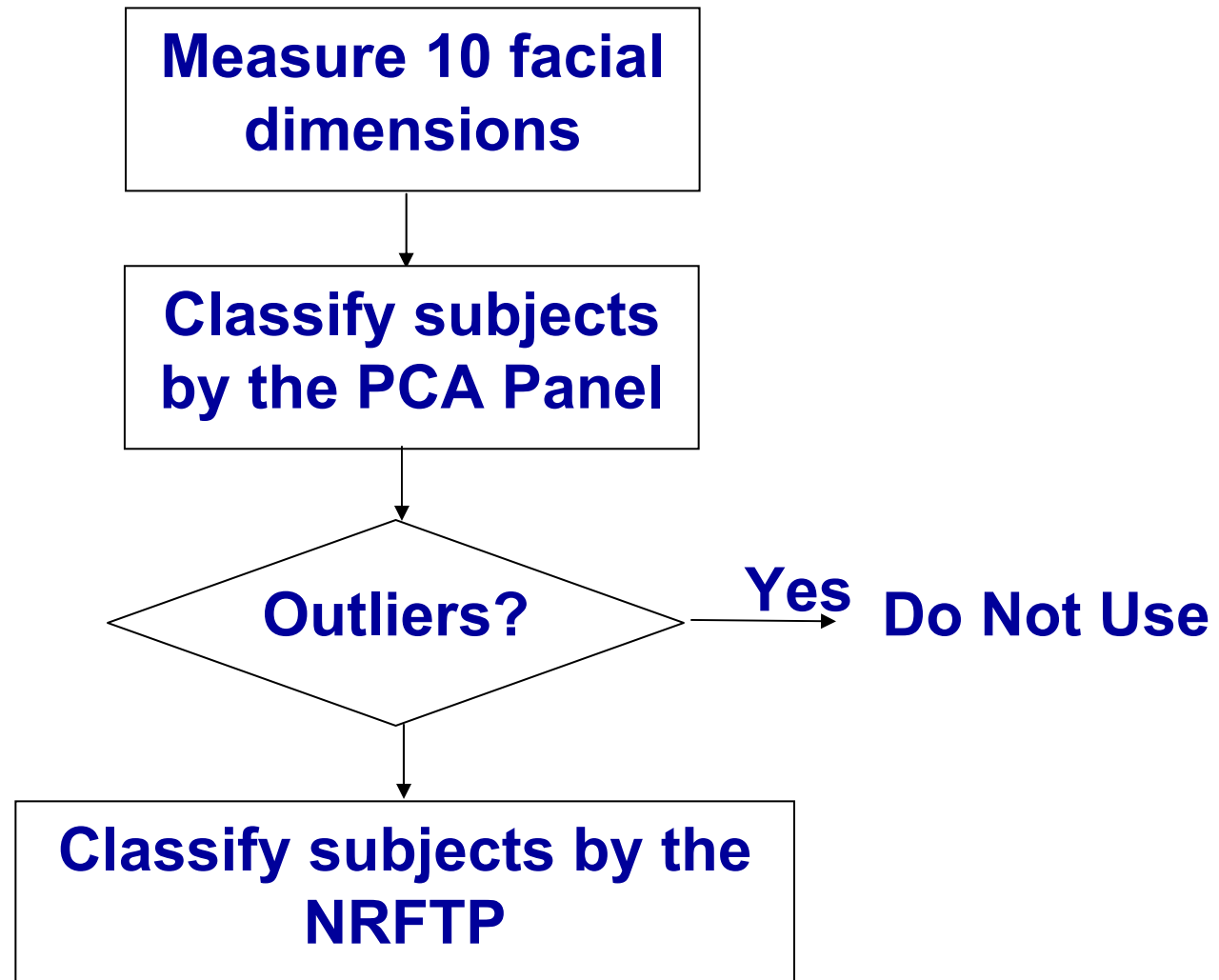
Total Inward Leakage Program

NRFTP

Total = 97.7% of US Respiratory Wearers

Face Width (mm)

Face Length (mm)

	120.5	132.5	134.5	144.5	146.5	158.5
138.5			5.2%		3.5%	
128.5	5.7%		21.3%		8.7%	
118.5	10.5%		25.0%		7.1%	
108.5	5.5%		5.3%			
98.5						

Total Inward Leakage Program

PCA Facial Shape Trends
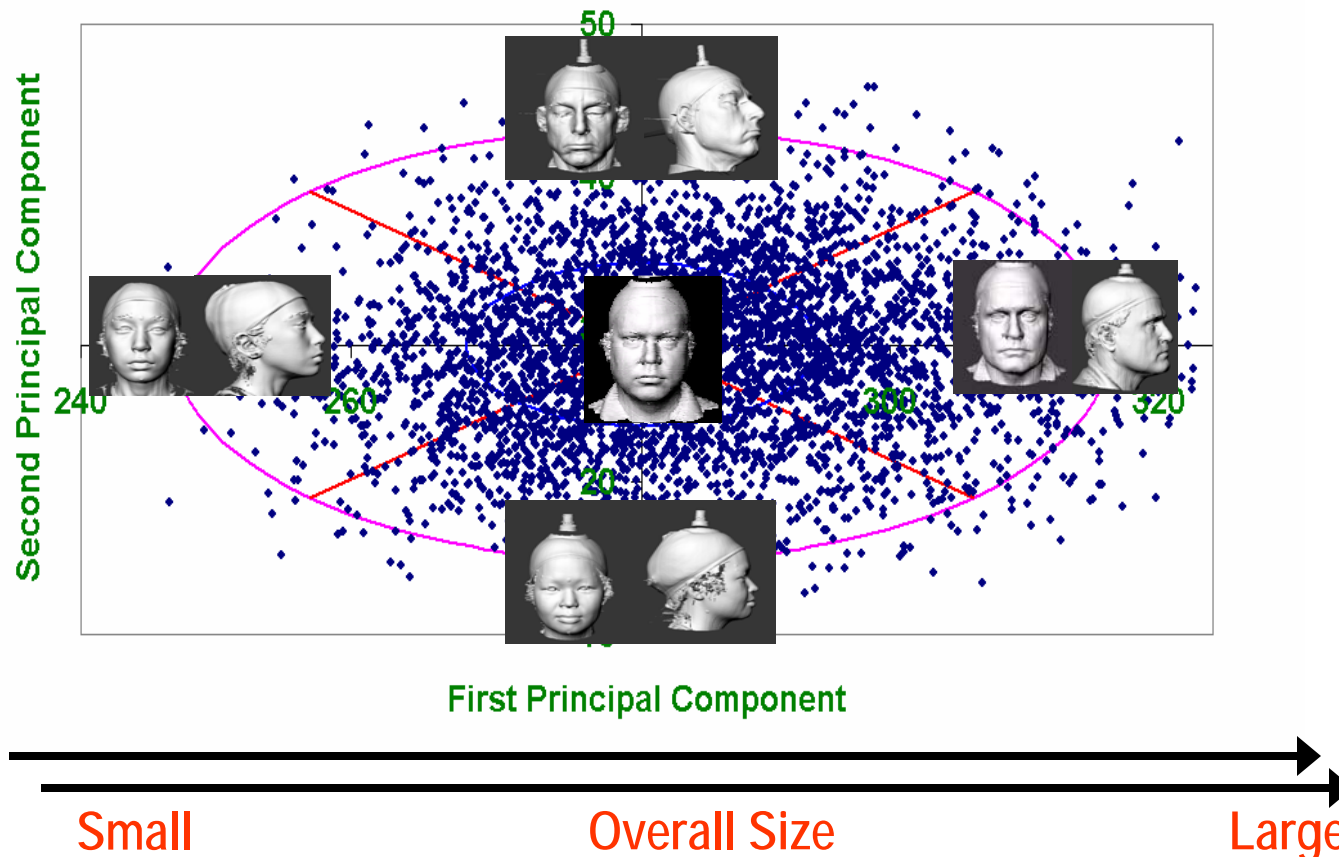
Total Inward Leakage Program

Subject Selection

- **Based on the NIOSH test panel**

  – Will screen out subjects not fitting into the PCA panel

- **Select 35 subjects for each facepiece**

  – Unlike what is done today

- **User instructions must dictate which subjects correspond to a given facepiece**

- **Correlation of respirator size to facial dimensions is not required to follow the NRFTP**

Total Inward Leakage Program

One size fits all facepiece
35 subjects

NRFTP

Face Width (mm)

Face Length (mm)

	120.5	132.5	134.5	144.5	146.5	158.5
138.5			2 (5.2%)		2 (3.5%)	
128.5	2 (5.7%)		7 (21.3%)		3 (8.7%)	
118.5	4 (10.5%)	9 (25.0%)				
108.5					2 (7.1%)	
98.5	2 (5.5%)	2 (5.3%)				

CDC Workplace Safety and Health

NIOSH

NPPTL Research to Practice through Partnerships

Total Inward Leakage Program

Small that fits
1, 2, 3 ,4 & 6
35 subjects

NRFTP

Face Width (mm)

Face Length (mm)	120.5	132.5 / 134.5	144.5 / 146.5	158.5
138.5 – 128.5	4 (5.7%)			
118.5	7 (10.5%)	16 (25.0%)		
108.5 – 98.5	4 (5.5%)	4 (5.3%)		

CDC Workplace Safety and Health

NIOSH

NPPTL Research to Practice through Partnerships

Total Inward Leakage Program

Large that fits
7, 8, 9 & 10
35 subjects

NRFTP

Face Width (mm)

Face Length (mm)

Total Inward Leakage Program

- ## **Test Protocol**
  - Instrumentation
    - TSI PortaCount® with Companion™ in direct reading mode
  - Challenge agent
    - Generated NaCl ≥500 particles/cc
  - Sample preparation
    - Flush probe located as close as possible between the subject's nose and mouth

Total Inward Leakage Program

- ## **Test Protocol**

  - Donning

    - Trained using the manufacturer's User Instructions

  - Pretest acclimation

    - Wait 5 minutes before starting

  - Exercises

    - OSHA exercises for 30 seconds/ exercise

Total Inward Leakage Program

- ## **Test Protocol**
  - Exercises
    - Normal breathing
    - Deep Breathing
    - Turning head from side to side
    - Moving head up and down
    - Recite the Rainbow Passage out loud
    - Reaching for the floor and ceiling
    - Grimace (not included in the TIL calculation)
    - Normal Breathing

Total Inward Leakage Program

- ## Test Protocol

  - Individual test TIL Calculation

    - TIL= Average penetration for the 7 exercises

  - Duplication

    - Each test is repeated three times for each subject/respirator combination

  - TIL Calculation

    - Average TIL for the three tests

Total Inward Leakage Program

- **Recap**
  - Each subject dons the respirator 3 times and completes a range of exercises
  - Calculate average penetration over all exercises
  - Calculate average over the 3 donnings
  - If penetration ≤ 5%, fit is considered acceptable
  - For each model (facepiece), count the number of subjects with acceptable fit (out of 35)
  - 26 of 35 must have an acceptable fit
  - TIL ≠ APF

Total Inward Leakage Program

- ## Cost
  - Estimated cost of testing each facepiece is $ 8,500 - $12,000

Total Inward Leakage Program

- ## Proposed Implementation Concept
  - Effective 30 days after codification
  - Applicable to all new approvals
  - 3 year grandfathering of old approvals

- ## Other Possible Scenarios
  - Process extensions of old approvals for 2 years
  - Comments and Suggestions welcome!

Docket Information

- **Mail:**
  - **NIOSH Docket Office**
  - **Robert A. Taft Laboratories, M/S C 34**
    - **TIL - NIOSH 036**
  - **4676 Columbia Parkway**
  - **Cincinnati, OH 45226**
- **Email: niocindocket@cdc.gov**
- **Fax: (513) 533-8285**
- **Phone: (513) 533-8303**
- **NPPTL Web Site: http://www.cdc.gov/niosh/npptl**

NPPTL Action Plan: Response to the IOM report on the Assessment of the NIOSH Head-and-Face Anthropometric Survey of Respirator Users

Ronald E. Shaffer
Chief, Research Branch
June 26, 2007

Overview

- **Objective**

  – Develop a long-term strategy ("Action Plan") for facial anthropometrics and respirator fit research at NPPTL to address the recommendations in the IOM report

- **Approach**

  – Analyze IOM recommendations to determine if existing data is available to make decisions on whether the recommendations could and/or should be implemented or not

  – Review on-going and proposed NPPTL research projects

  – Review on-going research in NIOSH, academia, government, and industry related to anthropometrics and respirator fit

Composition of Draft Action Plan

- **Part I. NPPTL assessment of IOM recommendations**

  – Detailed point by point response to each IOM recommendation.

- **Part II. Research Roadmap**

  – Prioritized 10 year plan for the sequence of research projects to address information gaps

DRAFT Roadmap

| 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |

Analysis of 2010 Census Data → **Evaluate Current Fit Test Panel**

NAS Report

Development of Improved Headforms

Biological shape analysis

Lab Study on Causative Factors Affecting Temporal Changes in FFR Fit

Decisions Needed:
1. Collect new data?
2. 3-D or traditional?
3. Key facial parameters

Half-Mask TIL rulemaking → **SWPF and WPF Studies of Post-TIL Certified Respirators**

Correlation of 3-D shape with respirator fit

Development of Standardized Methods for 3-D Head-scanning & Automated Facial Anthropometrics → **Data collection & analysis (3-D and/or traditional)** → **Updated Fit Test Panel (3-D or traditional)**

CDC Workplace Safety and Health   NIOSH   NPPTL Research to Practice through Partnerships

NPPTL Year Month Day File name

Next steps / Implementation of Action Plan

- **Detailed draft action plan posted to NPPTL website (July/August 2007)**

- **Open docket to solicit comments for 90 days (September – November 2007)**

- **Revise action plan based on comments received (January 2008)**

- **Action plan will be used to prioritize selection of future NPPTL research projects, funding, staffing, and equipment needs**

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